Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	47L9.20
True Name	Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live & Killed Virus, Leptospira Canicola-Grippotyphosa-Icterohaemorrhagiae-Pomona Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Duramune + 5L4 CV - No distributor specified Vanguard DAPP+L4+CV - No distributor specified Vanguard Plus - Zoetis Industria Produtos Veterinarios Ltda. Vanguard Plus - Zoetis Industria de Produtos Vanguard Plus 5 L4 CV - No distributor specified Vanguard Plus 5 L4 CV - Zoetis Argentina Vanguard Plus 5 L4 CV - Zoetis Colombia S.A.S. Vanguard Plus 5 L4 CV - Zoetis Israel Holding BV Vanguard Plus 5 L4 CV - Zoetis Japan Inc. Vanguard Plus 5 L4 CV - Zoetis Mexico Vanguard Plus 5 L4 CV - Zoetis Russia
Date of Compilation Summary	October 15, 2022

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy
Pertaining to	Canine Adenovirus Type 2 (CAV-2)
Study Purpose	Demonstrate effectiveness against CAV-2 and CAV-1
Product Administration	
Study Animals	Canine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	September 14, 1977

Study Type	Efficacy
Pertaining to	Canine Coronavirus (CCV)
Study Purpose	Demonstrate effectiveness against CCV
Product Administration	
Study Animals	Canine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	August 07, 1987

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Leptospira interrogans serovar Canicola</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate effectiveness against Leptospira interrogans serovar Canicola</td></tr>
<tr><td>Product Administration</td><td>Two doses, administered subcutaneously 3 weeks apart.</td></tr>
<tr><td>Study Animals</td><td>Study involved 16 vaccinated and 16 placebo puppies, 5-7 weeks of age.</td></tr>
<tr><td>Challenge Description</td><td>Challenged with Leptospira interrogans serovar Canicola, 25 days following administration of the second vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>After challenge, dogs were observed for 28 days for clinical signs of disease. Samples were collected post challenge to detect the presence of Leptospiral organisms.</td></tr>
<tr><td>Results</td><td>Efficacy was determined by Leptospirosis and Leptospiruria. Leptospirosis was based on culture of Leptospiral organisms from tissue samples (excluding blood, urine, and renal tissue) in conjunction with clinical signs of disease present on one or more days. Leptospiruria was defined as positive culture of Leptospiral organisms from urine or renal tissue.

Table 1: Number of animals with Leptospirosis
<table>
<tr><th rowspan="3">Treatment</th><th colspan="4">Leptospirosis</th><th rowspan="3">Total</th></tr>
<tr><th colspan="2">No</th><th colspan="2">Yes</th></tr>
<tr><th>No. of Animals</th><th>%</th><th>No. of Animals</th><th>%</th><th>No. of Animals</th></tr>
<tr><td>Placebo animals</td><td>0</td><td>0.00</td><td>16</td><td>100.00</td><td>16</td></tr>
<tr><td>Vaccinated animals</td><td>16</td><td>100.00</td><td>0</td><td>0.00</td><td>16</td></tr>
</table>
Table 2: Number of animals with Leptospiruria
<table>
<tr><th rowspan="3">Treatment</th><th colspan="4">Leptospiruria</th><th rowspan="3">Total</th></tr>
<tr><th colspan="2">No</th><th colspan="2">Yes</th></tr>
<tr><th>No. of Animals</th><th>%</th><th>No. of Animals</th><th>%</th><th>No. of Animals</th></tr>
<tr><td>Placebo animals</td><td>0</td><td>0.0</td><td>16</td><td>100.0</td><td>16</td></tr>
<tr><td>Vaccinated animals</td><td>16</td><td>100.0</td><td>0</td><td>0.0</td><td>16</td></tr>
</table></td></tr>
</table>

	The raw data for the animals is shown on the attached page.
USDA Approval Date	October 24, 2016

Table 3. Individual animal data for Leptospirosis

Treatment	Animal	Any Clinical Sign Present	Any Positive Culture of Leptospiral Organisms	Leptospirosis*
Placebo animals	4146	Yes	Yes	**Yes**
	2017	Yes	Yes	**Yes**
	4153	Yes	Yes	**Yes**
	4155	Yes	Yes	**Yes**
	2026	Yes	Yes	**Yes**
	2039	Yes	Yes	**Yes**
	4145	Yes	Yes	**Yes**
	4149	Yes	Yes	**Yes**
	2030	Yes	Yes	**Yes**
	2031	Yes	Yes	**Yes**
	2038	Yes	Yes	**Yes**
	4144	Yes	Yes	**Yes**
	2016	Yes	Yes	**Yes**
	2015	Yes	Yes	**Yes**
	2037	Yes	Yes	**Yes**
	2036	Yes	Yes	**Yes**
Vaccinated animals	4148	No	No	No
	2019	No	No	No
	4156	No	No	No
	4154	Yes	No	No
	2028	No	No	No

Treatment	Animal	Any Clinical Sign Present	Any Positive Culture of Leptospiral Organisms	Leptospirosis*
	2040	No	No	No
	4152	No	No	No
	4150	No	No	No
	2025	Yes	No	No
	2032	No	No	No
	2034	No	No	No
	4147	No	No	No
	2014	No	No	No
	2021	No	No	No
	2035	No	No	No
	2033	No	No	No

***** Leptospirosis was based on culture of Leptospiral organisms in conjunction with a clinical sign of disease.

Table 4. Individual animal data for Leptospiuria

Treatment	Animal	Leptospiruria*
Placebo animals	4146	**Yes**
	2017	**Yes**
	4153	**Yes**
	4155	**Yes**
	2026	**Yes**
	2039	**Yes**
	4145	**Yes**
	4149	**Yes**
	2030	**Yes**
	2031	**Yes**
	2038	**Yes**
	4144	**Yes**
	2016	**Yes**
	2015	**Yes**
	2037	**Yes**
	2036	**Yes**
Vaccinated animals	4148	No
	2019	No
	4156	No

Treatment	Animal	Leptospiruria*
	4154	No
	2028	No
	2040	No
	4152	No
	4150	No
	2025	No
	2032	No
	2034	No
	4147	No
	2014	No
	2021	No
	2035	No
	2033	No

* Leptospiruria was defined as positive culture of Leptospiral organisms from urine.

Table 5. Individual animal data for Control animals

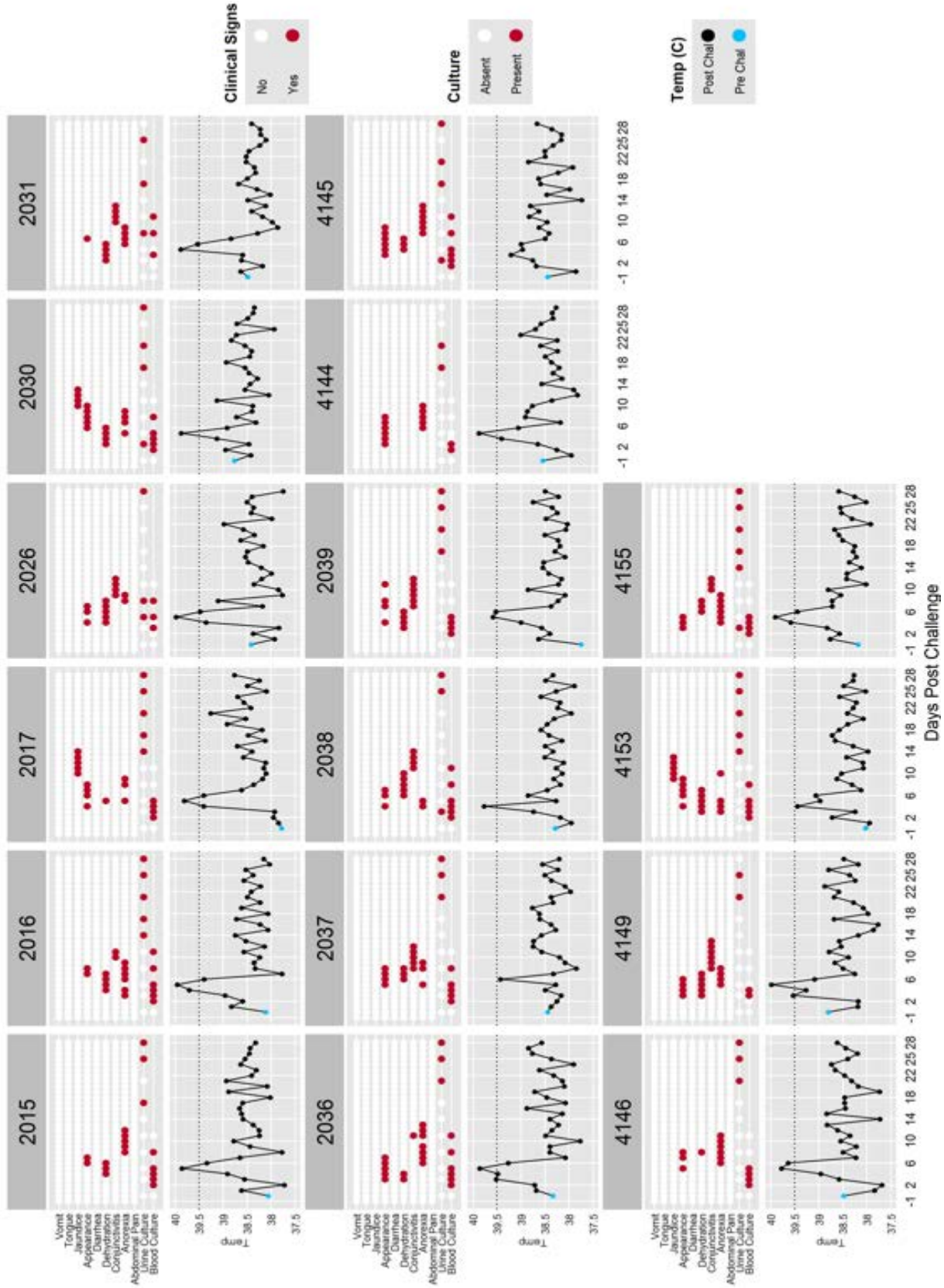
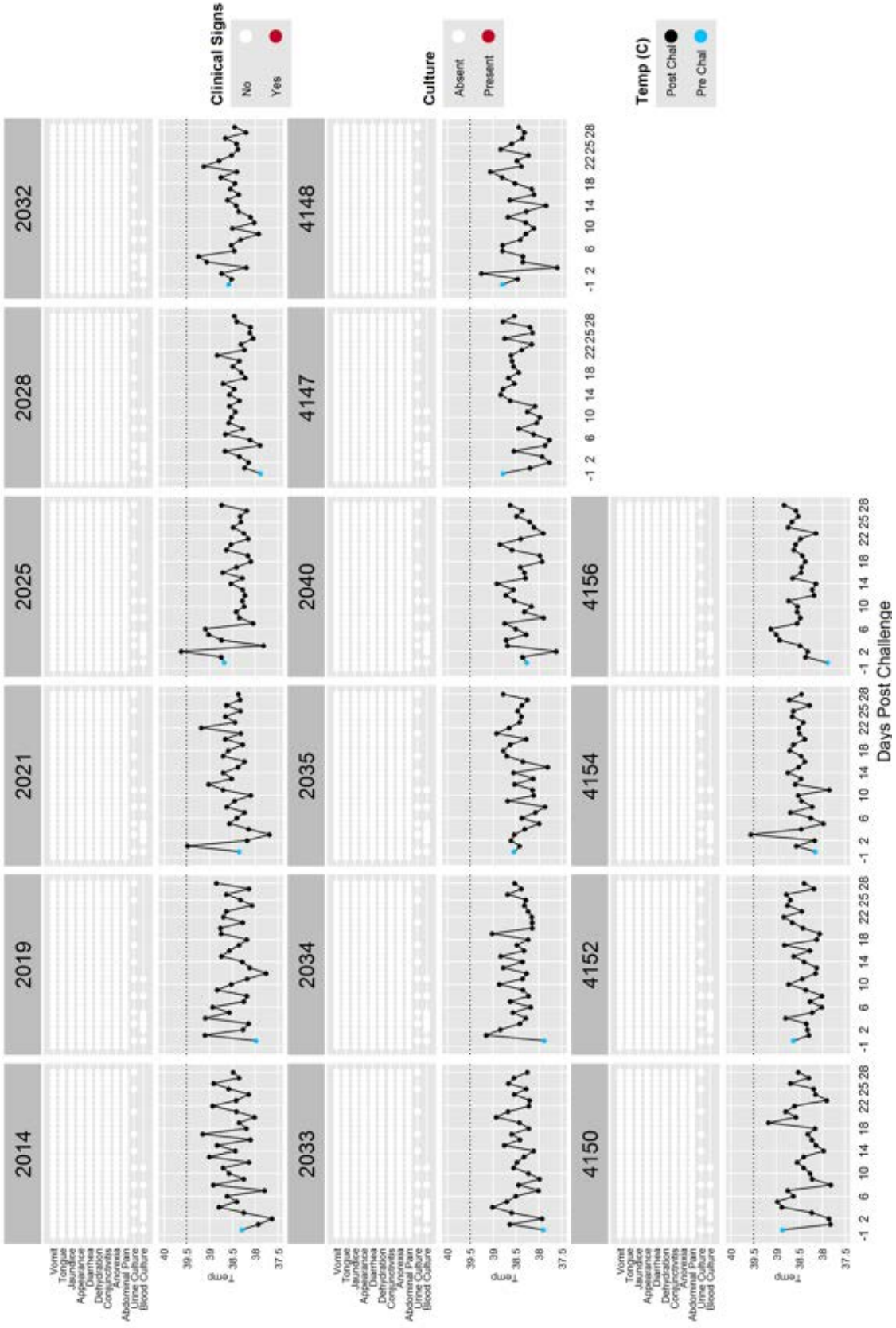


Table 6. Individual animal data for Vaccinated animals



Study Type	Efficacy
Pertaining to	*Leptospira Canicola*
Study Purpose	Demonstrate effectiveness against *L. canicola*
Product Administration	
Study Animals	Canine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	December 22, 2004

Study Type	Efficacy
Pertaining to	*Leptospira Grippotypohosa*
Study Purpose	Demonstrate effectiveness against *L. grippotypohosa*
Product Administration	
Study Animals	Canine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	June 03, 2004

Study Type	Efficacy
Pertaining to	*Leptospira Icterohaemorrhagiae*
Study Purpose	Demonstrate effectiveness against *L. icterohaemorrhagiae*
Product Administration	Subcutaneously
Study Animals	Canine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	December 22, 2004

Study Type	Efficacy
Pertaining to	*Leptospira Pomona*
Study Purpose	Demonstrate effectiveness against *L. pomona*
Product Administration	
Study Animals	Canine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	August 20, 2004

Study Type	Efficacy
Pertaining to	Canine Parainfluenza Virus (CPI)
Study Purpose	Demonstrate effectiveness against CPI
Product Administration	
Study Animals	Canine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	July 11, 1979

Study Type	Efficacy
Pertaining to	Canine Parainfluenza Virus (CPI)
Study Purpose	Demonstrate effectiveness against CPI
Product Administration	
Study Animals	Canine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	August 04, 1976

Study Type	Efficacy
Pertaining to	Canine Parainfluenza Virus (CPI)
Study Purpose	Demonstrate effectiveness against CPI
Product Administration	
Study Animals	Canine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	January 25, 1977

Study Type	Efficacy
Pertaining to	Canine Distemper Virus (CDV)
Study Purpose	Demonstrate effectiveness against CDV
Product Administration	
Study Animals	Canine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	November 15, 1976

Study Type	Efficacy
Pertaining to	Canine Distemper Virus (CDV)
Study Purpose	Demonstrate effectiveness against CDV
Product Administration	
Study Animals	Canine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	May 01, 1970

Study Type	Efficacy
Pertaining to	Canine Parvovirus (CPV)
Study Purpose	Demonstrate effectiveness against CPV
Product Administration	
Study Animals	Canine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	July 28, 1995

Study Type	Efficacy
Pertaining to	Canine parvovirus (CPV)
Study Purpose	To demonstrate efficacy against CPV Type 2c
Product Administration	Two doses, administered 3 weeks apart
Study Animals	30 beagles 6-8 weeks of age were randomly divided into either controls (T01, n=10) or vaccinates (T02, n=20)
Challenge Description	All animals were challenged 5 weeks after the second vaccination (study day 56) with CPV-2c orally and intranasally
Interval observed after challenge	Clinical observations and rectal body temperatures were observed twice daily for 2 weeks following challenge.
Results	Requirements per 9 CFR 113.317 were met. All dogs were negative for canine parvovirus serum neutralizing antibody and for fecal shedding of virus on Day 0 for the study. Control dogs remained negative through the day of challenge. All control dogs (10 of 10) met at least 3 criteria of parvovirus infection.* The vaccine was efficacious with no vaccinated dogs (0 of 20) having more than 1 criteria of infection, nor any virus shedding. *Criteria for CPV infection include: temperature ≥103.4 ˚F; lymphopenia of ≥50% of prechallenge normal; clinical signs such as diarrhea, mucus in feces, or blood in feces; and viral hemagglutinins at a level of ≥1:64 in a 1:5 dilution of feces or a test of equal sensitivity. Raw data is available on the following pages.
USDA Approval Date	August 22, 2011

Table 1. Individual animal listing (Infection)

Treatment	Animal	Fever	Lymphopenia	Clinical sign	Virus	Infected[1]
T01	1030703	YES	YES	YES	YES	YES
	1030707	YES	YES	YES	YES	YES
	1030802	NO	YES	YES	YES	YES
	1030905	YES	YES	YES	YES	YES
	1031002	NO	YES	YES	YES	YES
	1031004	NO	YES	YES	YES	YES
	1031101	YES	YES	YES	YES	YES
	1031104	YES	YES	YES	YES	YES
	1060903	NO	YES	YES	YES	YES
	1060904	YES	YES	YES	YES	YES

[1]Had at least 3 out of the 4 criteria for infection

Treatment	Animal	Fever	Lymphopenia	Clinical sign	Virus	Infected[2]
T02	1030701	NO	NO	NO	NO	NO
	1030702	NO	NO	NO	NO	NO
	1030704	NO	NO	NO	NO	NO
	1030705	NO	NO	NO	NO	NO
	1030706	NO	NO	NO	NO	NO
	1030801	NO	NO	YES	NO	NO
	1030901	NO	NO	YES	NO	NO
	1030902	NO	NO	NO	NO	NO
	1030904	NO	NO	NO	NO	NO
	1030906	NO	NO	YES	NO	NO
	1031001	NO	NO	NO	NO	NO
	1031003	NO	YES	NO	NO	NO
	1031005	NO	NO	NO	NO	NO
	1031006	NO	NO	NO	NO	NO
	1031102	NO	NO	NO	NO	NO
	1031103	NO	NO	YES	NO	NO
	1031105	NO	NO	NO	NO	NO
	1060901	NO	NO	NO	NO	NO
	1060902	NO	NO	NO	NO	NO
	1060905	NO	NO	NO	NO	NO

[2] Greater than one (>1) out of four criteria of infection

Table 2.1. Rectal temperature first week post-challenge (study days 56-62.1)

Trtmt***	Animal	56	56.1**	57	57.1**	58	58.1**	59	59.1**	60	60.1**	61	61.1**	62	62.1**
T01	1030703	101.2	101.9	101.1	101.6	100.9	100.9	100.8	101.4	101.8	103.9	101.8			
T01	1030707	101.7	100.7	101.8	101.0	101.3	101.4	101.7	102.3	102.0	103.6	102.8	101.5	102.0	
T01	1030802	101.6	101.4	101.6	101.3	101.1	101.2	101.2	101.5	101.2	101.6	102.0	101.7	101.0	
T01	1030905	101.6	100.8	101.6	100.1	101.4	101.7	102.0	101.5	102.1	103.6	101.9	101.5	101.9	
T01	1031002	101.7	101.4	100.7	101.2	101.0	102.1	101.1	101.6	101.4	101.6	102.6			
T01	1031004	101.2	100.6	100.8	100.3	100.9	101.5	101.0	101.7	101.5	102.0	101.7			
T01	1031101	101.2	100.8	100.8	101.2	101.1	101.3	101.2	102.0	102.3	103.7	102.6	101.9	102.8	
T01	1031104	102.9	101.4	101.7	101.0	101.4	101.8	102.0	103.2	104.3	104.3	102.2	103.0	101.7	
T01	1060903	101.2	100.6	101.6	100.9	101.5	101.0	101.3	100.7	102.7	101.9	102.4			
T01	1060904	102.2	101.1	102.2	101.8	102.0	102.1	102.0	102.2	103.0	103.5	102.6			
T02	1030701	101.0	101.1	101.3	101.2	101.2	101.8	101.1	100.3	101.3	101.3	100.9	101.6	101.5	101.3
T02	1030702	101.1	100.8	101.4	100.6	101.3	101.5	101.0	101.4	100.8	101.6	101.0	101.2	101.2	101.8
T02	1030704	100.8	100.5	100.8	100.9	100.6	101.0	100.6	101.2	101.0	100.8	100.9	101.1	101.2	100.7
T02	1030705	101.4	100.5	102.1	101.5	101.6	101.5	101.5	101.8	101.4	102.1	101.3	101.3	101.8	101.7
T02	1030706	101.2	100.9	101.4	101.1	101.1	100.9	101.1	101.4	101.3	101.0	101.3	101.1	101.7	101.1
T02	1030801	101.1	100.6	101.8	101.3	101.3	101.4	101.0	100.6	101.2	101.1	101.8	101.1	101.6	101.3
T02	1030901	101.5	101.6	101.7	101.2	101.9	101.5	101.6	101.9	101.6	101.7	101.7	101.2	101.8	101.4
T02	1030902	101.0	101.0	101.4	101.2	101.3	101.3	101.3	101.3	100.8	101.1	100.4	101.4	101.3	101.8
T02	1030904	100.9	101.3	102.1	101.2	101.7	101.4	102.2	102.1	101.9	102.2	101.6	101.7	102.1	101.9
T02	1030906	101.1	100.9	101.4	100.9	101.3	101.5	101.2	101.4	100.9	101.2	101.2	101.5	101.4	101.4
T02	1031001	101.1	101.0	100.9	101.4	101.6	101.3	101.4	101.9	100.8	101.2	101.6	101.3	101.9	101.1
T02	1031003	101.0	100.9	101.7	101.3	101.3	102.6	101.7	101.6	101.3	101.2	102.1	101.7	101.7	101.5
T02	1031005	101.1	100.7	101.2	101.5	101.3	102.1	101.3	101.7	101.6	101.7	101.4	101.6	101.5	101.5
T02	1031006	101.4	100.5	101.2	101.5	101.0	101.6	101.2	100.9	101.2	101.4	101.4	101.5	101.7	101.5
T02	1031102	100.3	100.7	100.9	101.2	100.8	100.5	100.8	100.8	100.2	101.2	100.6	100.7	100.2	101.1
T02	1031103	101.0	100.3	101.1	100.9	101.9		101.2	101.7	101.1	101.9	101.2	101.4	101.1	101.1
T02	1031105	101.3	100.8	101.1	100.8	101.3	101.3	101.3	100.8	101.1	101.5	101.2	101.3	101.6	101.2
T02	1060901	100.9	100.9	101.2	101.2	101.7	101.5	102.0	101.2	102.1	101.3	102.1	101.9	102.1	101.9
T02	1060902	101.4	101.2	101.8	101.0	101.9	101.1	101.6	100.8	101.9	101.8	101.6	101.4	102.0	101.4
T02	1060905	100.5	100.9	101.3	100.7	101.0	101.4	101.0	101.4	101.1	101.2	101.0	100.9	101.8	101.5

* Highlighting indicates animal(s) with rectal temperature (≥103.4°F); Fever. ** PM ***Treatment; Animals in treatment group T01 were euthanized on study D61 [(n=5) 5 days post challenge] and study D62 [(n=5) 6 days post challenge] as a result of clinical signs associated with challenge.

Table 2.2. Rectal temperature second week post-challenge (study days 63-70)

Trtmt*	Animal	63	63.1**	64	64.1**	65	65.1**	66	66.1**	67	67.1**	68	68.1**	69	69.1**	70
T01***	1030703															
T01	1030707															
T01	1030802															
T01	1030905															
T01	1031002															
T01	1031004															
T01	1031101															
T01	1031104															
T01	1060903															
T01	1060904															
T02	1030701	101.2	100.8	101.7	101.0	101.2	101.3	101.6	100.9	101.2	101.1	101.7	101.4	101.2	101.1	101.8
T02	1030702	101.0	101.2	101.2	101.2	101.1	100.7	101.1	101.2	101.1	101.8	100.9	101.2	100.7	100.3	101.6
T02	1030704	100.6	100.7	101.1	100.5	101.0	100.3	101.3	100.6	101.2	100.8	100.8	100.9	101.3	100.7	101.1
T02	1030705	101.9	101.5	102.0	101.5	101.7	101.4	101.6	101.3	101.4	101.2	101.6	101.7	101.6	101.8	101.8
T02	1030706	101.3	101.2	101.1	100.9	101.3	100.9	101.6	101.1	101.5	101.5	101.4	100.9	101.3	101.4	101.6
T02	1030801	101.5	100.7	101.8	101.8	101.3	100.9	101.6	101.3	101.3	101.0	101.5	101.2	101.6	101.0	101.9
T02	1030901	102.0	101.0	101.9	100.8	101.9	100.8	101.7	101.0	101.5	101.3	101.4	101.3	101.6	101.2	101.4
T02	1030902	101.6	101.0	101.4	101.3	101.4	101.2	101.4	101.2	101.3	101.3	100.9	101.4	101.3	101.3	101.1
T02	1030904	102.9	101.5	102.9	102.2	102.6	101.6	102.3	101.8	102.3	101.8	102.4	102.4	102.4	101.7	102.1
T02	1030906	101.7	100.8	101.3	101.4	101.3	101.1	101.2	101.1	101.4	100.9	101.2	100.7	101.1	100.9	101.1
T02	1031001	100.9	100.6	101.1	101.0	101.0	100.5	101.1	100.9	101.1	100.7	100.5	101.4	101.0	100.7	101.5
T02	1031003	101.3	101.4	101.6	100.4	101.8	101.1	101.6	101.4	101.1	101.3	101.8	100.8	101.6	101.2	101.1
T02	1031005	101.7	101.1	101.4	100.8	101.5	100.8	101.6	101.5	101.5	101.6	101.4	101.4	101.6	101.3	101.5
T02	1031006	101.6	101.5	101.5	101.3	101.3	101.1	101.6	101.2	101.3	101.0	101.4	101.2	101.5	101.2	101.1
T02	1031102	100.9	101.3	100.7	100.9	100.7	100.6	100.5	100.5	101.0	100.8	100.7	100.7	100.4	100.8	100.5
T02	1031103	101.5	100.9	101.2	100.7	101.4	101.1	101.2	101.1	101.6	101.0	101.2	101.4	101.0	100.6	101.6
T02	1031105	101.4	101.2	101.6	101.2	101.6	101.2	101.5	101.4	101.3	101.2	101.7	101.5	101.2	100.4	102.1
T02	1060901	101.6	100.8	101.8	101.4	101.7	101.2	101.9	101.7	101.8	101.8	101.1	100.5	101.6	101.2	101.2
T02	1060902	101.8	100.6	101.7	101.2	101.8	101.4	101.7	101.0	101.9	100.6	101.8	101.4	101.6	101.7	101.9
T02	1060905	101.1	100.3	101.2	100.8	101.1	101.0	101.6	100.7	101.6	101.1	101.6	101.0	101.0	100.8	100.4

*Treatment ** PM ***Animals in treatment group T01 were euthanized on study D61 [(n=5) 5 days post challenge] and study D62 [(n=5) 6 days post challenge] as a result of clinical signs associated with challenge.

Table 3. Summary of lymphocyte absolute values (10^3/UL) study days 54 to 69 (D54-69)

Animal	Trt***	D54	D55	D56	D57	D58	D59	D60	D61	D62	D63	D64	D65	D66	D67	D68	D69
1030703	T01	6.08	5.90	4.65	4.90	4.08	4.17	0.87	0.79								
1030707	T01	4.82	5.43	5.31	3.75	5.50	4.25	1.40	1.11	1.09							
1030802	T01	6.83	5.67	5.75	5.69	5.03	5.56	1.93	1.22	1.97							
1030905	T01	3.17	3.48	3.32	2.93	3.47	3.32	0.94	0.77	1.14							
1031002	T01	6.79	6.51	5.23	6.16	5.22	5.42	1.60	0.75								
1031004	T01	4.36	3.94	3.27	2.83	3.15	2.17	0.66	0.90								
1031101	T01	4.91	4.00	3.07	3.44	3.60	1.87	0.81	1.23	1.27							
1031104	T01	4.66	4.26	3.08	4.47	3.49	1.93	0.38	1.36	2.00							
1060903	T01	4.62	4.84	3.73	3.95	3.71	2.68	1.27	0.79								
1060904	T01	3.47	4.08	3.40	3.09	3.46	2.65	1.72	1.06								
1030701	T02	4.18	4.02	3.50	3.91	3.29	3.27	3.13	3.01	3.55	3.43	4.10	4.01	3.43	3.89	3.86	3.50
1030702	T02	6.13	6.41	6.05	4.72	4.77	5.78	5.46	4.19	5.83	5.62	5.75	6.58	7.21	6.24	5.22	6.65
1030704	T02	4.12	5.32	5.47	4.80	5.47	6.15	6.89	6.11	6.46	6.86	6.2	5.44	5.39	6.00	5.31	5.23
1030705	T02	7.26	6.58	5.89	5.06	6.10	5.13	4.84	4.99	5.30	6.08	5.24	5.57	6.13	5.54	5.19	5.95
1030706	T02	4.40	4.30	3.98	3.71	4.79	4.19	3.98	3.82	3.66	4.50	3.52	3.35	4.14	3.19	4.14	3.53
1030801	T02	4.93	4.78	3.25	4.08	4.2	4.44	4.29	4.30	3.71	3.75	4.12	3.59	4.02	4.40	3.87	3.69
1030901	T02	3.54	4.63	3.04	5.52	3.37	3.65	3.29	3.74	3.75	3.64	3.70	3.6	3.73	4.01	3.78	3.90
1030902	T02	4.89	4.00	3.47	3.44	3.65	3.29	3.67	3.88	3.52	4.54	3.93	3.67	3.67	4.08	3.83	3.77
1030904	T02	4.64	5.85	5.31	3.94	4.94	5.41	4.78	5.01	4.74	4.82	5.21	4.88	4.37	4.94	6.01	5.64
1030906	T02	3.23	2.94	2.93	3.00	3.11	3.04	2.75	2.50	2.56	2.81	2.56	3.01	2.55	2.78	2.88	2.60
1031001	T02	4.40	4.82	3.67	3.48	3.91	4.40	4.20	3.83	3.83	4.12	5.00	3.62	4.26	4.49	4.22	3.84
1031003	T02	4.31	4.27	2.99	3.10	3.17	3.02	2.65	3.16	3.53	0.69	3.57	3.44	3.69	4.00	3.46	3.65
1031005	T02	3.71	3.80	2.89	2.73	2.57	2.67	2.89	2.69	2.96	3.01	3.50	3.49	3.17	3.70	3.65	3.26
1031006	T02	5.54	4.86	3.26	3.29	3.71	3.68	3.30	3.57	3.59	4.04	4.01	3.43	3.60	4.17	4.08	3.49
1031102	T02	3.67	3.83	3.73	2.98	3.14	2.59	3.20	2.94	2.68	3.41	3.35	3.36	2.74	4.18	3.68	3.63
1031103	T02	4.12	4.88	4.33	4.36	3.39	3.16	3.77	3.72	3.21	4.08	3.16	4.27	4.21	4.49	4.29	4.66
1031105	T02	3.80	4.28	3.05	3.59	3.72	3.32	3.81	3.48	3.21	4.64	4.30	3.92	3.71	4.12	4.27	3.84
1060901	T02	5.83	5.28	4.53	4.74	4.42	4.66	4.19	4.73	4.18	4.98	4.47	4.24	5.07	5.25	4.81	4.61
1060902	T02	3.35	3.45	3.23	3.59	3.66	3.48	3.63	3.53	3.28	4.18	3.61	3.71	3.88	3.59	3.70	3.57
1060905	T02	3.58	3.28	2.45	2.43	2.68	2.82	2.69	2.36	2.54	2.96	2.81	2.63	2.74	2.87	3.02	2.61

* Highlighting indicates animal(s) with lymphopenia; reduction in lymphocytes [≥ 50 percent of pre-challenge normal (average of the three pre-challenge values)].
**Normal range = 1.3 to 4.1 (10^3 / uL); Advia 120. ***Treatment group; Animals in treatment group T01 were euthanized on study D61 [(n=5) 5 days post challenge] and study D62 [(n=5) 6 days post challenge] as a result of clinical signs associated with challenge.

Table 4. Summary of white blood cell absolute values (10^3/UL) study days 54 to 70 (D54-70)

Animal	Trt**	D54	D55	D56	D57	D58	D59	D60	D61	D62	D63	D64	D65	D66	D67	D68	D69
1030703	T01	13.46	13.10	11.36	10.89	10.85	11.06	8.73	4.58								
1030707	T01	11.78	12.27	11.33	8.54	11.90	10.67	10.92	8.36	3.57							
1030802	T01	13.87	11.93	11.65	12.03	11.63	11.46	10.24	11.04	6.80							
1030905	T01	6.91	7.05	7.18	6.92	9.08	7.56	8.35	5.02	5.98							
1031002	T01	14.84	21.06	12.54	17.27	14.72	14.47	15.38	12.06								
1031004	T01	11.03	9.70	10.51	8.29	9.46	9.97	11.29	12.01								
1031101	T01	11.63	9.60	9.60	10.88	9.44	7.65	8.01	4.03	5.92							
1031104	T01	9.01	8.59	6.56	9.58	8.26	8.72	9.33	3.01	5.15							
1060903	T01	10.31	10.32	8.12	8.56	8.68	7.81	10.18	13.09								
1060904	T01	10.32	11.98	8.96	9.08	10.10	8.74	13.34	13.20								
1030701	T02	9.82	9.44	7.62	8.21	7.76	9.05	8.14	7.35	8.03	8.57	9.79	9.04	8.51	9.34	9.24	8.48
1030702	T02	13.10	13.00	14.69	13.84	13.18	13.19	13.72	11.61	14.46	14.09	13.28	13.80	15.19	15.00	14.70	15.60
1030704	T02	20.84	13.6	9.56	12.31	11.34	14.22	14.92	14.11	15.93	18.73	16.08	13.70	14.61	15.10	12.60	11.50
1030705	T02	14.03	12.39	11.63	12.34	11.90	10.88	10.34	9.86	11.83	12.60	11.79	11.00	17.89	13.9	12.40	12.50
1030706	T02	10.01	10.42	9.17	9.11	12.34	9.53	8.89	8.61	8.29	9.94	9.36	8.56	10.43	9.54	10.40	8.77
1030801	T02	10.15	10.55	8.35	9.04	9.04	8.70	9.21	9.10	8.88	8.27	9.05	8.23	9.85	9.55	8.57	8.50
1030901	T02	8.04	11.35	7.84	9.12	8.39	8.52	7.94	8.00	9.39	8.22	8.37	7.52	7.89	9.11	9.04	9.02
1030902	T02	9.99	19.34	12.33	10.71	10.01	10.63	11.26	10.85	11.07	12.25	10.52	11.00	10.72	14.40	13.2	10.70
1030904	T02	11.96	14.59	14.81	12.33	13.44	14.78	12.32	12.41	12.28	12.44	14.40	12.6	12.71	14.10	15.00	13.90
1030906	T02	9.19	9.23	8.25	8.40	8.61	7.36	7.46	7.25	7.06	8.01	7.39	8.24	7.60	7.95	8.05	7.57
1031001	T02	10.57	10.70	8.85	7.71	8.45	9.04	9.16	8.55	8.92	8.61	10.98	8.02	9.47	9.83	10.10	9.64
1031003	T02	13.32	10.61	9.73	9.31	10.55	9.88	9.85	9.56	10.88	10.43	11.43	9.67	11.26	13.00	11.90	11.70
1031005	T02	8.10	8.53	7.02	7.60	7.85	6.48	6.88	6.46	7.77	8.09	8.47	8.18	7.81	8.51	9.00	8.64
1031006	T02	14.14	10.87	7.90	10.91	10.79	10.37	8.48	9.08	10.23	10.57	11.03	8.04	9.27	10.80	10.80	8.75
1031102	T02	8.31	8.53	8.43	11.96	9.83	6.72	7.40	6.51	6.85	8.42	7.63	7.82	6.36	9.94	8.76	8.18
1031103	T02	10.17	13.17	9.59	10.93	8.57	7.76	8.64	8.89	7.84	9.24	8.27	8.84	9.42	11.20	10.2	11.90
1031105	T02	8.63	9.21	7.62	8.17	8.02	7.23	8.49	7.92	7.35	9.53	9.27	8.77	8.31	9.16	9.40	10.20
1060901	T02	12.40	11.77	10.68	11.68	11.24	10.45	9.65	10.31	9.56	10.94	10.11	9.02	10.72	12.10	11.5	10.90
1060902	T02	9.61	10.78	9.64	9.75	9.74	8.62	9.57	9.70	8.89	9.95	10.15	9.29	10.21	10.10	11.00	9.90
1060905	T02	9.97	9.04	7.60	7.87	8.13	8.41	9.17	7.61	7.34	8.88	8.48	7.93	8.38	9.04	8.97	8.11

*Normal range = 5.2 to 13.9 (10^3 / uL); Advia 120. **Treatment group; Animals in treatment group T01 were euthanized on study D61 [(n=5) 5 days post challenge] and study D62 [(n=5) 6 days post challenge] as a result of clinical signs associated with challenge.

Table 5. Summary of clinical signs by treatment Study Day 56* to Day 70														
	Diarrhea		Vomit		Dehydration		Mucus in stool		Blood in stool		Anorexia		Lethargy	
	Yes		Yes		Yes		Yes		Yes		Yes		Yes	
Treatment	no.	%	no.	%	no.	%	no.	%	no.	%	no.	%	no.	%
T01 (Control)	10	100	9	90	2	20	9	90	7	70	8	80	3	30
T02 (CPV-2c)	4	20	2	10	0	0	2	10	0	0	0	0	0	0

*Day of challenge

Table 6. Summary of virus isolation results by treatment group and Study Day

		Virus Isolation*				Total
		Negative		Positive		
		No. of Observations	%	No. of Observations	%	No. of Observations
Treatment	DOS	10	100	0	0.0	10
T01**	56					
	57	9	90	1	0.0	10
	58	10	100	0	0.0	10
	59	7	70	3	10	10
	60	0	0	10	90	10
	61	0	0	10	100	10
	62	0	0	5	100	5
	63	0	0	0	0	0
	64	0	0	0	0	0
	65	0	0	0	0	0
	66	0	0	0	0	0
	67	0	0	0	0	0
	68	0	0	0	0	0
	69	0	0	0	0	0
	70	0	0	0	0	0
T02	56	20	100	0	0	20
	57	20	100	0	0	20
	58	20	100	0	0	20
	59	20	100	0	0	20
	60	20	100	0	0	20
	61	20	100	0	0	20
	62	20	100	0	0	20
	63	20	100	0	0	20
	64	20	100	0	0	20
	65	20	100	0	0	20
	66	20	100	0	0	20
	67	20	100	0	0	20
	68	20	100	0	0	20
	69	20	100	0	0	20
	70	20	100	0	0	20

*Negative ($\leq 10^{3.0}$ $TCID_{50}$ / gram), positive ($\geq 10^{3.3}$ $TCID_{50}$ / gram).

**Animals in treatment group T01 were euthanized on study D61 [(n=5) 5 days post challenge] and study D62 [(n=5) 6 days post challenge] as a result of clinical signs associated with challenge.

Study Type	Efficacy
Pertaining to	Canine Parvovirus (CPV)
Study Purpose	Demonstrate effectiveness against CPV in the face of low levels of maternal antibody.
Product Administration	
Study Animals	Canine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	July 03, 1995

Study Type	Safety
Pertaining to	Canine Adenovirus Type 2 (CAV-2)
Study Purpose	Safety Evaluation to demonstrate the development of corneal opacity is not associated with the use of this product.
Product Administration	
Study Animals	Dogs
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	15 August, 1977

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety under field conditions
Product Administration	
Study Animals	Canine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	January 28, 2005