



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1599.24
True Name	Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live & Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Canine Spectra 6 - Peak Marketing Solo-Jec 6 - No distributor specified
Date of Compilation Summary	June 02, 2020

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	Infectious Canine Hepatitis Virus									
Study Purpose	To demonstrate effectiveness against Infectious Canine Hepatitis (ICH)									
Product Administration	Two doses were administered subcutaneously (SC) 21 days apart									
Study Animals	Seventeen (17) 6-week-old puppies, seronegative for ICH, were randomly sorted into 1 group of 11 SC vaccinates and one group of 6 controls.									
Challenge Description	21 days after second vaccination all dogs were challenged with Infectious Canine Hepatitis Virus.									
Interval observed after challenge	Puppies were observed for 21 days after challenge for clinical signs.									
Results	<p>The study was satisfactory per the criteria in 9 CFR 113.305(1)(ii) (A)(B)</p> <table border="1" data-bbox="587 920 1230 1115"> <thead> <tr> <th></th> <th>Mortality</th> <th>Clinical Signs of CDV Infection</th> </tr> </thead> <tbody> <tr> <td>SC Vaccinates</td> <td>0/11 (0%)</td> <td>0/11 (0%)</td> </tr> <tr> <td>Controls</td> <td>6/6 (100%)</td> <td>6/6 (100%)</td> </tr> </tbody> </table>		Mortality	Clinical Signs of CDV Infection	SC Vaccinates	0/11 (0%)	0/11 (0%)	Controls	6/6 (100%)	6/6 (100%)
	Mortality	Clinical Signs of CDV Infection								
SC Vaccinates	0/11 (0%)	0/11 (0%)								
Controls	6/6 (100%)	6/6 (100%)								
USDA Approval Date	March 31, 1998									

Canine Infectious Hepatitis Clinical Signs Observed Post Challenge																			
Dog	Treatment	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC	15DPC	16DPC	
1	Control					22	N/A												
2	Control					1,4,7,20	1,3,5,6,15,17,20,22***												
3	Control				3,13,23**	1,3,23,22***	N/A												
4	Control				23**	1,3,7	1,3,6,7,17,20,22***												
5	Control			23*	3	22	N/A												
6	Control			7	7	22	N/A												
19	SC Vac																		
20	SC Vac																		
21	SC Vac																		
22	SC Vac																	6	
23	SC Vac																		
24	SC Vac									6									
25	SC Vac																		
26	SC Vac																		
27	SC Vac																		
28	SC Vac																		
29	SC Vac								6									6	
	1 - Depression/Lethargy					6 - Serous ocular discharge			15 - Excessive Salivation					23 - Other					
	3- Dehydration					7 - Mild/Moderate mucopurulent			17 - Icteric Gums					* Icteric Lumbar only					
	4 - Mild/Moderate Conjunctivitis					Ocular Discharge			20 - Petechial Pain /					** Icteric lumbar and ears					
	5 - Severe Conjunctivitis					13 - Vomiting			Ecchymotic					***- moribund and euthanization					
						NO Clinical signs observed in any group after 16DPC			22 - Death					DPC – Days post challenge					

Study Type	Efficacy
Pertaining to	Canine Adenovirus Type II
Study Purpose	To demonstrate effectiveness against Canine Adenovirus Type II (CAV2)
Product Administration	Two doses were administered subcutaneously 21 days apart
Study Animals	Twenty-two (22) 6-week-old puppies seronegative for CAV2 were randomly sorted into one group of 11 SC vaccinates and one group of 11 controls.
Challenge Description	21 days after second vaccination all dogs were challenged with CAV2
Interval observed after challenge	Puppies were observed for 21 days after challenge for clinical signs.
Results	<p>The study was considered satisfactory by the reduction in clinical signs and virus shedding in the vaccinates when compared to the control animals.</p> <p>See the next page for data.</p>
USDA Approval Date	April 3, 1998

CAV2 Clinical Signs Observed Post Challenge

Dog	Group	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC	15DPC	16DPC	17DPC	18DPC	19DPC	20DPC	21DPC
1	Control						1	1,2			2	2											
2	Control						1	1,2	1,2	1,2	2	2											
3	Control						1	1,2	1	1	1	1											
4	Control						1,2	1,2	1,2,4	1,2,	2	2											
5	Control						1	1	1,4	1	1	1											
6	Control					2		4			1	1								1	1		
7	Control						1	1,2,4	1,2,4,5,6	1	1	2,4	1	1,2	1	1,2	1	1,2					
8	Control		1	1,2	1,2	1	1,2	1,6	1	1	1	1	1	1	1	1	1	1	1				
9	Control						1	1	1	4	4	4											
10	Control					1	1	1	1	1	1,2			1									
11	Control					2		1,2	1,2	1	1	1											
23	SC																						
24	SC																						
25	SC						1			1													
26	SC																						
27	SC																						
28	SC							1															
29	SC							1	1														
30	SC		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
31	SC						1	1	1	1	1,2												
32	SC																						
33	SC																						
		1 - Ocular Discharge		3 - Sneezing		5 - Retching		7 - Inappetence		Blank - No Clinical signs observed													
		2 - Nasal Discharge		4 - Coughing		6 - depression/lethargy																	

DPC - Days Post Challenge

CAV2 Isolation from Nasal Swab Samples (TCID₅₀/100ul)

Dog	Group	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC	15DPC	16DPC	17DPC	18DPC	19DPC	20DPC	21DPC
1	Control				2	2.5	3.63	3.5	≤1.83														
2	Control				2	2.83	3.5	3.83	2.17								≤1.83						
3	Control				≤1.63	3.5	4.17	3.38								2.17							
4	Control					2.63	3.38	4.31	2.35				≤1.63										≤1.63
5	Control				2.38	2.6	4.38	3.6	≤2.63														
6	Control				≤1.83	≤1.83	4.5	3.63	3.63														
7	Control				≤1.63	2.75	4.5	4.5	≤1.83														
8	Control				2.38	2.83	3.63	3.17															
9	Control				≤1.63	2.83	2.83	4.38															
10	Control				≤1.63	2.17	3.63	3.5					≤1.63	2.38	2.5	≤1.83						≤1.83	
11	Control				≤1.83	2.5	4.5	4.38						≤1.63	≤1.83	≤1.63	≤1.63				≤1.63		≤1.63
23	SC																						
24	SC		≤1.6				2.38																
25	SC					≤1.63																	≤1.63
26	SC								2.63														
27	SC												≤1.63										
28	SC																						
29	SC				2	≤1.83																	
30	SC																						
31	SC																						
32	SC						≤1.83	2.63	2.5														
33	SC																						
Blank - No CAV2 titer detected																							
DPC - Days Post Challenge																							

Study Type	Efficacy
Pertaining to	Canine coronavirus
Study Purpose	To demonstrate effectiveness against intestinal disease due to canine coronavirus
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance. Study data, however, are no longer available.
USDA Approval Date	December 3, 1984

Study Type	Efficacy
Pertaining to	Canine Parainfluenza Virus
Study Purpose	To demonstrate effectiveness against Canine Parainfluenza Virus (CPI)
Product Administration	Two doses were administered by the subcutaneous (SC) route three (3) weeks apart
Study Animals	Nineteen (19) 6-week-old puppies seronegative for CPI were randomly sorted into one group of 13 SC vaccinates and one group of 6 controls.
Challenge Description	21 days after second vaccination all dogs were challenged with CPI
Interval observed after challenge	Puppies were observed for 21 days after challenge for clinical signs. Blood and nasal swabs were collected during this period.
Results	<p>The study was considered satisfactory based on the serologic response in vaccinates and the decrease in the number of days of virus shedding in vaccinates when compared to controls.</p> <p>See the next page for data.</p>
USDA Approval Date	March 16, 1998

**CPI Serum Neutralization
Antibody Titers**

Controls										
Dog	ODPV1	14DPV1	ODPV2	7DPV2	14DPV2 (w)	14DPV2	21DPV2	7DPC	14DPC	21DPC
1	<2	<2	<2	<2	<2	<2	<2	2	28	65
2	<2	<2	<2	<2	<2	<2	<2	1	99	182
3	<2	<2	<2	<2	<2	<2	<2	1	81	280
4	<2	<2	2	<2	<2	<2	<2	3	46	221
5	<2	<2	<2	<2	<2	<2	<2	2	71	289
6	<2	<2	<2	<2	<2	<2	<2	4	64	182

SQ Vaccinates										
Dog	ODPV1	14DPV1	ODPV2	7DPV2	14DPV2 (w)	14DPV2	21DPV2	7DPC	14DPC	21DPC
20	<2	<2	<2	<2	10	36	42	1248	7281	6295
21	<2	<2	<2	<2	3	16	6	2892	5880	4742
22	<2	<2	<2	<2	<2	18	6	1446	7037	3622
23	<2	<2	<2	<2	4	46	10	1152	10809	4581
24	<2	<2	<2	<2	<2	3	3	1579	4562	4096
25	<2	<2	<2	<2	<2	<2	<2	811	2884	10139
26	<2	<2	<2	<2	<2	<2	<2	227	793	661
27	<2	<2	<2	<2	<2	27	12	789	7079	5754
28	<2	<2	<2	<2	<2	<2	4	878	2253	2655
29	<2	<2	<2	<2	<2	16	5	1330	9462	7228
30	<2	<2	<2	<2	<2	3	3	373	1151	724
31	<2	<2	<2	<2	<2	<2	<2	2048	2281	2586
32	<2	<2	<2	2.2	<2	<2	3	1833	1193	880

DPV - Days Post Vaccination

DPC - Days Post Challenge

A titer of <2 is considered seronegative

CPI Virus Isolation from Nasal Swabs

Controls															
Dog	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1	-	+	+	+	+	+	+	-	-	-	-	-	-	-	-
2	-	+	+	+	+	+	+	-	-	-	-	-	-	-	-
3	-	+	+	+	+	+	+	-	+	-	-	-	-	-	-
4	-	+	+	+	+	+	+	-	+	-	-	-	-	-	-
5	-	+	+	+	+	+	+	+	-	-	-	-	-	-	-
6	-	+	+	+	+	+	+	+	+	-	-	-	-	-	-

SC Vaccinates															
Dog	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
20	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
21	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
22	-	+	+	+	+	+	-		+	-	-	-	-	-	-
23	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
24	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
25	-	+	+	+	+	+	-	-	+	-	-	-	-	-	-
26	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
27	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
28	-	+	+	+	+	+	+	-	+	-	-	-	-	-	-
29	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
30	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
31	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
32	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-

- means CPI virus was not detected
 + means CPI virus was detected

Study Type	Efficacy									
Pertaining to	Canine Distemper Virus (CDV)									
Study Purpose	To demonstrate effectiveness against CDV									
Product Administration	Two doses were administered subcutaneously 21 days apart									
Study Animals	Seventeen (17) 6-week-old puppies seronegative for CDV were randomly sorted into 1 group of 11 SC vaccinates and one group of 6 controls.									
Challenge Description	21 days after second vaccination all dogs were challenged with CDV.									
Interval observed after challenge	Dogs were observed for 42 days after challenge for clinical signs of CDV.									
Results	<p>The study was satisfactory per the criteria in 9 CFR 113.306 (b)(3) (i-ii)</p> <table border="1" data-bbox="587 887 1230 1079"> <thead> <tr> <th></th> <th>Mortality</th> <th>Clinical Signs of CDV Infection</th> </tr> </thead> <tbody> <tr> <td>SC Vaccinates</td> <td>0/11 (0%)</td> <td>0/11 (0%)</td> </tr> <tr> <td>Controls</td> <td>5/6 (83%)</td> <td>6/6 (100%)</td> </tr> </tbody> </table> <p>See the next page for data.</p>		Mortality	Clinical Signs of CDV Infection	SC Vaccinates	0/11 (0%)	0/11 (0%)	Controls	5/6 (83%)	6/6 (100%)
	Mortality	Clinical Signs of CDV Infection								
SC Vaccinates	0/11 (0%)	0/11 (0%)								
Controls	5/6 (83%)	6/6 (100%)								
USDA Approval Date	April 6, 1998									

Study Type	Efficacy
Pertaining to	Canine Parvovirus (CPV)
Study Purpose	To demonstrate effectiveness against CPV in 6-week-old puppies.
Product Administration	Two doses, given at an interval of 21 days, were administered subcutaneously (SC).
Study Animals	Study analysis was conducted on twenty-one (21) 6-week-old puppies seronegative for CPV, 17 vaccinates and 4 non-vaccinated controls.
Challenge Description	Twenty-one (21) days after second vaccination puppies were challenged with CPV 2b strain.
Interval observed after challenge	Puppies were observed daily for 14 days after challenge
Results	<p>The data were analyzed according to 9 CFR 113.317.</p> <p>Number affected by challenge according to 9 CFR 113.317:</p> <p>Vaccinates: 0/17 (0%) Controls: 2/4 (50%)</p> <p>See the next page for data.</p>
USDA Approval Date	August 31, 2001

CPV Post Challenge Daily Observations

Non-Vaccinated Controls															
Dog ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1		D					E,H								
2							B,C,H	C	C						
3					H	D	B,G,H	I							
4						G,H	B,C,D,F,G,H	I							

Vaccinates															
Dog ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1															
2															
3	D						H				E				
4															
5											D				
6															
7												E			
8															
9															
10										D					
11		D				D									
12															
13			D												
14															
15															
16															
17															

B - Lethargy
 C - Dehydration
 D - Mucous Stool
 E - Watery Stool
 F - Bloody Stool
 G - Anorexia
 H - Vomiting
 I - Death
 DPC = Days Post Challenge

Daily Rectal Temperature (°F)

Non-Vaccinated Controls															
Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1	100.4	101.3	101.3	101.1	102.1	101.9	100.7	101.3	101.3	101.0	100.8	101.4	100.6	101.4	101.2
2	99.7	101.2	101.7	100.9	103.0	102.6	99.3	101.0	101.0	101.0	101.5	101.6	101.3	102.4	102.0
3	101.2	101.6	102.5	101.3	104.5	101.3	100.0	Na							
4	100.4	101.2	101.4	101.2	104.1	101.7	93.4	Na							

Vaccinates

Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
5	101.1	101.9	101.2	101.3	101.7	101.5	101.0	101.0	101.5	101.7	101.1	101.8	101.7	101.3	101.8
6	101.1	100.5	101.5	101.3	101.1	101.5	101.5	101.3	101.7	101.6	101.4	101.7	101.7	101.3	102.1
7	101.0	100.5	101.0	100.8	101.3	101.1	100.6	100.5	101.4	101.2	100.9	101.0	101.3	101.4	100.8
8	100.7	100.9	101.4	101.7	101.4	101.1	101.3	101.3	101.7	101.4	101.3	101.4	101.2	100.9	102.3
9	101.0	101.0	101.4	101.5	101.2	101.0	101.3	101.1	101.3	101.5	101.6	101.7	101.5	101.3	101.8
10	101.3	101.9	102.1	101.5	102.0	101.6	101.1	101.4	101.5	101.8	102.3	102.4	102.5	102.7	102.0
11	100.5	100.8	101.0	101.2	100.9	100.8	100.8	101.2	101.3	101.0	101.2	101.0	101.3	101.1	101.6
12	99.7	100.7	101.5	101.1	101.1	101.3	100.9	101.0	101.1	101.1	101.1	101.3	101.0	101.3	101.2
13	100.5	101.6	102.1	101.0	101.2	101.0	101.1	100.9	101.5	101.3	101.7	102.3	101.4	101.8	102.1
14	101.3	100.8	101.6	101.4	101.2	101.2	100.6	100.9	101.1	101.1	101.1	101.2	101.1	101.0	101.6
15	101.3	101.5	102	101.8	102.1	102.2	101.8	101.5	102.3	102.3	101.7	102.5	101.9	102.1	102.2
16	100.9	102.2	101.4	101.5	101.4	101.8	101.3	101.5	101.0	101.2	101.3	101.6	101.4	101.8	101.9
17	99.9	100.4	101.8	101.3	101.0	101.5	100.3	101.7	101.1	101.3	101.1	101.1	101.2	101.1	101.3
18	99.7	101.1	101.0	101.4	101.0	101.4	101.5	100.7	100.7	100.4	101.4	100.8	101.0	100.5	101.7
19	100.7	101.2	101.1	101.0	101.6	101.4	100.8	100.7	101.4	101.8	101.2	101.4	101.3	101.7	102.3
20	100.9	102.1	101.9	101.7	101.8	102.5	100.9	101.3	101.6	101.9	101.7	101.3	101.4	101.8	102.3
21	101.8	101.6	102.0	102.1	101.2	101.9	100.8	101.3	101.7	101.4	101.6	101.2	101.4	101.2	101.7

DPC = Days Post Challenge

Total White Blood Cell Counts (x1000/uL)

Non-Vaccinated Controls											
Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC
1	12.3	10.7	13.2	11.5	11.2	13.9	8.2	9.0	9.7	10.5	10.3
2	9.9	12.3	14.4	11.7	17.0	12.7	13.0	7.5	10.0	9.0	12.9
3	20.6	18.0	23.0	Na	30.2	15.6	13.7	Na	Na	Na	Na
4	14.7	18.4	17.4	17.4	19.9	6.3	0.3	Na	Na	Na	Na

Vaccinates											
Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC
5	10.2	11.8	11.8	8.4	10.3	12.7	9.18	9.1	9.8	10.3	10.7
6	11.0	10.2	12.7	11.0	9.3	10.1	9.61	9.8	10.3	9.3	10.0
7	13.5	9.0	9.3	9.1	9.4	10.2	8.73	8.9	10.9	10.0	8.4
8	11.9	10.4	10.2	10.0	9.0	9.3	8.40	8.6	8.2	8.4	9.7
9	12.5	12.8	12.8	10.3	9.7	9.3	8.17	8.1	8.2	7.3	7.3
10	12.7	13.7	15.1	12.3	9.9	10.0	8.00	10.2	20.3	12.0	9.9
11	11.3	11.7	9.8	Na	9.4	8.8	7.71	10.7	18.9	8.8	14.9
12	27.2	18.5	21.8	15.3	13.9	10.4	10.70	12.1	11.2	10.8	10.1
13	7.8	17.6	16.1	15.1	11.0	11.2	11.80	11.5	14.1	13.9	9.5
14	20.4	21.6	17.6	Na	20.4	14.0	17.10	14.1	11.4	10.0	10.3
15	16.7	17.6	14.5	12.6	10.6	10.9	11.0	10.4	10.3	14.2	23.2
16	21.6	18.5	16.0	16.0	16.0	14.7	12.6	15.4	12.0	12.8	13.1
17	13.6	10.8	9.1	Na	9.3	12.7	7.8	9.9	11.0	14.4	8.5
18	12.4	14.8	11.0	14.6	14.7	14.9	11.8	9.4	9.4	10.0	8.8
19	37.0	28.2	27.7	20.0	21.9	28.6	17.2	20.3	16.3	17.7	16.2
20	19.0	21.3	18.7	17.4	18.9	28.2	14.1	19.6	18.3	19.6	16.2
21	16.7	11.6	14.3	15.9	12.8	14.4	12.9	14.5	10.1	12.1	14.3

DPC = Days Post Challenge

CPV Titer From Fecal Material (Log FAID₅₀/mg Feces)

Non-Vaccinated Controls											
Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC
1	<1.5	<1.5	<1.5	<1.5	2.4	4.2	5.8	5.5	5.2	2.0	1.5
2	<1.5	<1.5	<1.5	<1.5	1.5	3.8	5.6	5.4	4.5	3.5	3.4
3	<1.5	<1.5	<1.5	<1.5	3.2	5.5	NS	NS	NS	NS	NS
4	<1.5	<1.5	<1.5	<1.5	3.5	NS	6.2	NS	NS	NS	NS

Vaccinates											
Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC
5	<1.5	<1.5	<1.5	<1.5	<1.5	NS	<1.5	<1.5	<1.5	<1.5	<1.5
6	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
7	<1.5	<1.5	<1.5	<1.5	<1.5	NS	<1.5	<1.5	<1.5	<1.5	<1.5
8	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
9	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
10	<1.5	<1.5	<1.5	<1.5	<1.5	NS	<1.5	<1.5	<1.5	<1.5	<1.5
11	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
12	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
13	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
14	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
15	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
16	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
17	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
18	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
19	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
20	<1.5	<1.5	<1.5	<1.5	<1.5	NS	<1.5	<1.5	<1.5	<1.5	<1.5
21	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5

<1.5 is considered negative
 NS = No sample
 DPC = Days Post Challenge

C

Study Type	Efficacy
Pertaining to	Canine Parvovirus (CPV)
Study Purpose	To demonstrate effectiveness against CPV
Product Administration	Two doses given at an interval of 28 days were administered subcutaneously (SC).
Study Animals	Twenty-five (25) 6-week-old puppies seropositive for parvovirus; 20 vaccinates and 5 non-vaccinated controls.
Challenge Description	Fifty-six days (56) after second vaccination puppies were challenged with CPV type 2c strain.
Interval observed after challenge	Puppies were observed for clinical signs daily for 14 days after challenge
Results	<p>Dogs were determined affected by the criteria of 9 CFR 113.317(c)(3)(i).</p> <p>Number affected:</p> <p>Vaccinates: 1/20 (5%) Controls: 4/5 (80%)</p> <p>See the next page for data.</p>
USDA Approval Date	January 31, 2012

CPV Post challenge Clinical Observations

Non-Vaccinated Controls															
Dog ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
9						1,2,3	1,2,3	1,2,3	2,3,4	Na	Na	Na	Na	Na	Na
11						1,2,3	1,2,3	1,2,3	2,3						
19						1	1	1	1						
21								2,3	1,3						
27															

Vaccinates															
Dog ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1														1,3	
2															
3											1				
4	1														
5															
6															
7															
8	1														
10															
13															
14															
15														1	
16															1
17									1	2					
18															
20															
22															
23	1														
24															
28															

1 - Mucous Stool 3-Bloody Stool Blank - No clinical signs observed
 2-Diarrhea (Watery stool) 4-Death

DPC – Days post challenge

Serum Neutritization Titer								
Non-Vaccinated Controls								
Dog ID	-24DPV1	0DPV1	7PV1	28DPV1 (0DPV2)	41DPV1	56DPV1	70DPV1	84DPV1 (0DPC)
9	724	8	4	<2	<2	<2	<2	<2
11	91	4	3	<2	<2	<2	<2	<2
19	23	64	23	<2	<2	<2	<2	<2
21	<2	11	10	<2	<2	<2	<2	<2
27	10	8	6	<2	<2	<2	<2	<2

Vaccinates								
Dog ID	-24DPV1	0DPV1	7PV1	28DPV1 (0DPV2)	41DPV1	56DPV1	70DPV1	84DPV1 (0DPC)
1	91	32	8	<2	1024	11585	11585	=>23170
2	64	32	23	<2	362	6871	16384	16384
3	54	45	23	2	1024	5793	5793	6871
4	153	64	23	<2	724	19534	23170	=>46341
5	2048	45	16	<2	45	4096	8192	23170
6	1024	23	23	<2	<2	512	2896	9767
7	1448	6	4	<2	1024	8192	8192	=>23170
8	512	32	8	<2	<2	2896	11585	=>46341
10	128	45	64	2	<2	11585	11585	11585
13	181	6	6	<2	45	2048	5793	8192
14	32	8	16	2	<2	2896	4884	11585
15	23	6	2	<2	512	11585	11585	16384
16	8	11	11	2	<2	9767	11585	23170
17	32	32	23	5	<2	11585	8192	16384
18	16	23	19	<2	512	23170	11585	11585
20	45	11	4	<2	724	8192	16384	11585
22	<2	11	8	<2	4	8192	11585	8192
23	2	8	11	<2	1448	NO TEST	16384	11585
24	4	11	4	<2	1024	16384	23170	16384
28	128	32	16	<2	1448	4096	11585	9767

DPV1 - Days post first Vaccination 0DCP - Days post challenge
 DPV2 - Days Post Second Vaccination

Lymphocyte Counts Post Challenge (x10³/µl)

CatID	Controls													
	-2DPC	-1DPC	0DPC	Average	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC
9	1.24	1.20	1.38	1.27	1.71	1.45	0.80	0.30	0.28	0.74	0.27	Na	Na	Na
11	2.24	2.59	2.07	2.30	2.28	2.36	1.82	0.29	0.58	0.69	1.04	1.17	1.27	2.13
19	1.57	2.14	1.87	1.86	2.32	2.26	2.42	1.42	0.70	1.59	1.66	1.52	2.11	2.70
21	1.67	2.19	2.52	2.13	2.68	1.92	2.31	1.17	0.67	1.75	2.03	1.52	2.09	3.35
27	2.68	2.26	2.30	2.41	2.29	2.37	2.25	0.92	1.00	1.09	2.04	1.74	2.08	2.60

CatID	Vaccinates													
	-2DPC	-1DPC	0DPC	Average	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC
1	3.05	3.06	2.74	2.95	2.05	2.25	2.42	2.39	2.66	3.31	2.57	3.01	2.64	3.14
2	2.45	2.50	2.34	2.43	3.32	3.05	3.27	3.03	2.73	3.20	3.23	2.92	3.28	1.67
3	2.09	2.40	2.34	2.28	2.42	2.46	2.32	1.65	1.73	2.38	2.16	2.42	2.52	2.10
4	1.10	1.59	2.46	1.72	3.23	2.45	2.91	2.03	2.75	2.34	2.41	2.87	2.66	3.12
5	0.62	0.96	1.16	0.91	1.23	1.32	1.14	1.26	1.19	1.57	1.49	1.36	1.09	1.98
6	1.43	1.84	1.73	1.67	1.84	1.55	1.16	1.79	1.62	2.44	1.97	2.32	2.24	2.77
7	1.23	1.22	1.18	1.21	1.18	1.51	1.53	1.68	1.52	1.81	0.22	1.67	1.91	2.33
8	2.07	1.89	2.00	1.99	1.81	1.93	1.78	1.52	1.64	2.52	2.23	2.51	2.59	2.38
10	2.74	2.80	3.27	2.94	1.93	2.43	2.56	3.01	2.65	2.44	2.65	2.64	2.83	2.76
13	1.26	2.25	2.24	1.92	2.43	1.88	2.57	2.39	2.57	3.09	3.22	3.24	3.17	2.72
14	2.17	2.24	3.02	2.48	3.57	3.62	3.76	3.28	3.07	3.66	4.10	4.18	4.57	4.83
15	2.21	2.30	2.66	2.39	3.10	2.81	3.04	2.85	2.98	3.29	2.51	0.93	2.71	2.59
16	1.68	2.54	2.06	2.09	2.56	2.08	3.35	2.83	2.35	3.13	2.90	2.27	3.24	3.30
17	2.25	2.14	2.11	2.17	2.42	2.84	2.62	2.93	2.69	3.04	2.78	1.34	2.59	3.28
18	2.06	2.82	2.50	2.46	2.97	2.48	2.62	3.05	3.04	3.98	3.27	2.26	3.98	4.78
20	1.83	2.11	2.05	2.00	2.58	2.22	2.39	2.50	1.73	1.98	2.12	2.28	2.35	3.26
22	3.80	3.05	3.35	3.40	3.96	3.18	3.38	3.75	2.36	2.42	3.93	3.23	3.34	4.33
23	0.84	1.46	1.51	1.27	1.63	1.35	1.47	1.45	1.29	1.72	1.53	1.44	1.14	1.22
24	0.97	2.04	2.32	1.78	2.09	2.24	2.67	2.03	2.03	2.70	2.46	2.68	2.86	3.54
28	2.43	2.68	2.15	2.42	2.68	2.89	3.56	3.56	2.52	2.46	3.57	3.61	3.50	0.92

DPC – Days post challenge

Body Temperature Post Challenge °F

Non-Vaccinated Controls											
Dog ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC
9	102.0	102.0	102.6	102.9	103.2	104.6	103.2	100.9	Na	Na	Na
11	102.6	102.9	102.6	102.6	103.1	103.4	102.8	102.2	101.3	101.5	102.2
19	102.5	102.8	102.1	102.3	101.9	103.8	102.3	102.4	101.6	102.1	101.9
21	102.2	102.3	101.3	101.4	102.0	103.4	102.0	101.8	101.5	101.5	101.4
27	102.2	102.1	102.1	102.7	102.5	102.8	103.0	102.4	100.9	101.6	101.9

Vaccinates											
Dog ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC
1	101.9	102.0	101.9	101.9	101.7	102.0	101.5	101.9	101.3	101.6	101.7
2	102.7	103.5	103.1	103.1	103.5	102.3	103.1	102.9	102.4	102.6	102.6
3	103.0	103.0	102.5	102.2	102.7	102.7	103.1	103.0	102.1	102.5	101.9
4	101.6	102.4	102.3	102.1	102.4	102.1	103.4	102.7	102.1	102.1	102.1
5	103.5	103.4	103.2	103.3	103.5	102.6	102.8	103.4	102.8	103.1	102.7
6	102.7	102.6	101.7	102.8	102.4	102.4	102.8	102.7	102.2	102.4	102.1
7	101.7	102.5	102.5	103.3	103.0	103.1	103.1	103.1	102.9	102.6	102.1
8	102.7	102.9	102.5	102.4	102.6	102.2	102.2	102.5	101.7	101.2	102.2
10	103.1	103.3	102.3	102.8	103.0	102.5	102.2	102.7	102.8	101.9	101.9
13	103.0	102.5	102.8	102.2	103.2	102.6	102.7	103.0	102.4	102.9	102.7
14	102.3	102.8	102.4	102.4	102.7	102.4	102.6	102.4	102.0	101.9	102.1
15	102.5	102.7	102.3	102.0	102.8	102.2	102.4	102.4	101.9	102.2	101.7
16	101.7	102.5	102.8	101.9	102.5	102.1	102.1	101.9	101.5	101.1	101.6
17	101.9	102.8	102.3	102.6	102.7	102.1	102.0	101.9	102.0	101.7	102.1
18	102.2	102.5	102.1	101.5	102.3	102.6	102.0	102.0	101.9	101.8	102.0
20	102.2	101.9	101.9	102.0	102.2	101.8	101.8	101.9	101.6	101.4	101.9
22	102.7	102.9	102.4	101.8	102.8	102.5	102.5	102.8	102.0	102.0	101.9
23	102.5	102.8	102.7	102.7	103.2	102.4	102.7	103.1	102.1	102.4	102.2
24	103.3	103.1	102.6	102.2	102.5	102.4	102.2	102.2	102.1	101.8	102.3
28	102.2	102.1	102.0	102.4	102.2	102.2	102.0	102.0	101.8	101.5	101.6

DPC – Days post challenge

Fecal Virus Isolation Titer Post Challenge

CatID	Controls										
	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC
9	≤1.5	≤1.5	≤1.5	≤1.5	≤2.5	6.6	7.6	5.2	≥9.2	Na	Na
11	≤1.5	≤1.8	≤1.5	≤1.5	5.5	7.2	7.5	≥8.5	≥8.6	≥7.6	6.6
19	≤1.5	≤1.5	≤1.5	≤1.5	2.5	4.2	7.5	7.6	4.2	4	≤1.5
21	≤1.5	≤1.5	≤1.5	≤1.8	4.3	4.7	6.3	6.8	≤2.8	4.5	3.6
27	≤1.5	≤1.5	≤1.5	≤1.5	≤2.8	5.2	7.4	6.6	5.2	≤3.0	≤1.5

CatID	Vaccinates										
	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC
1	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
2	≤1.5	≤1.8	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
3	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
4	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
6	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
7	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
8	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
10	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
13	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
14	≤1.5	≤1.6	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
15	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
16	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
17	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
18	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
20	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
22	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
23	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
24	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
28	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤2.5	≤1.5	≤2.5	≤1.5	≤1.5	≤1.5

Positive For CPV >1.5 log¹⁰ FAID₅₀/mL

DPC – Days post challenge

Study Type	Safety
Pertaining to	Canine Adenovirus Type-2 (CAV-2)
Study Purpose	Development of corneal opacity is not associated with the use of this product
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data are not available.

Study Type	Safety
Pertaining to	All fractions
Study Purpose	Demonstrate safety of product under typical use conditions
Product Administration	Either one or two doses of vaccine 2-4 weeks apart by the subcutaneous route. A total of 1231 doses were administered.
Study Animals	A total of 621 dogs, 358 under 6 weeks of age and 263 greater than 6 weeks of age, privately owned and from commercial kennels were enrolled in the study.
Challenge Description	Not applicable
Interval observed after challenge	No challenge. Observed for 30 minutes after vaccination and then daily for 2 weeks after each vaccination.
Results	Results are summarized below.
USDA Approval Date	November 15, 2002

Summary of Reactions:

Reaction Type	Puppies up to 6 weeks of age				Dogs > 6 Weeks of Age				Sum of Doses	Reaction Rate
	<24hr	>24hrs	Total Reactions by dose	%	<24hr	>24hrs	Total Reactions by dose	%		
None	NA	NA	696	97.21%	NA	NA	506	98.25%	1202	97.64%
Salivation	0	0	0	0.00%	1	0	1	0.19%	1	0.08%
Lethargy	3	6	9	1.26%	0	0	0	0.00%	9	0.73%
Anorexia	3	10	13	1.82%	0	0	0	0.00%	13	1.06%
Injection Site Swelling	0	4	4	0.56%	0	1	1	0.19%	5	0.41%
Injection Site Pain	3	0	3	0.42%	5	0	5	0.97%	8	0.65%
Facial Swelling	0	0	0	0.00%	1	0	1	0.19%	1	0.08%
Vomiting or Diarrhea	3	0	3	0.42%	1	0	1	0.19%	4	0.32%
Mortality*	0	0	0	0.00%	2	0	2	0.39%	2	0.16%
Total Doses	716				515				1231	

*Confirmed by cooperator to be due to causes other than vaccination.

Some dogs had more than one adverse event, so total events do not agree with doses administered.