

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	46B9.21
True Name	Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza- Parvovirus Vaccine, Modified Live & Killed Virus, Borrelia Burgdorferi Bacterin-Leptospira Canicola-Grippotyphosa- Icterohaemorrhagiae-Pomona Bacterial Extract
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Duramune Lyme + Max 5-CvK/4L - Elanco US Inc.
Date of Compilation Summary	December 20, 2019

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.

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Study Type	Efficacy									
Pertaining to	Infectious Canir									
Study Purpose	To demonstrate (ICH)	effectiveness ag	gainst Infectious C	anine Hepatitis						
Product Administration	Two doses were	administered s	ubcutaneously (SC	2) 21 days apart						
Study Animals	` /	* *	pies, seronegative							
	-		of 11 SC vaccinat	es and one						
	group of 6 contr									
Challenge Description	•		n all dogs were cha	allenged with						
	Infectious Canir									
Interval observed after	Puppies were ob	served for 21 d	ays after challenge	e for clinical						
challenge	signs.									
Results	_	atisfactory per t	the criteria in 9 CF	R 113.305						
	(1)(ii)(A)(B)									
	_		1	1						
	Mortality Clinical Signs of									
		Wiortanty	CDV Infection							
	SC Vaccinates	0/11 (0%)	0/11 (0%)							
	Controls	6/6 (100%)	6/6 (100%)							
USDA Approval Date	March 31, 1998									

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Dog	Treatment	ODPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC 1	ODPC 11D	PC 12DP	C 13DPC	14DPC	15DPC	16DP
1	Control					22	N/A	1			ll_		-	1	l		
2	Control					1,4,7,20	1,3,5,6,15,17,20,22***										
3	Control				3,13,23**												
4	Control				23**	1,3,7	1,3,6,7,17,20,22***					N/	4				
5	Control			23*	3	22	N/A										
6	Control			7	7	22	N/A										
	CONTENT			,	•		1,77.										
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	on/Letl	nargy			6 - Serous oc	ular discharge		15 - Ex	cessive	Salivatio	n	23 - 0	Other			
	3- Dehydrati	on				7 - Mild/Mod	derate mucopurulent	17 - Icteric Gums * Icteric Lumbar o		bar only	,						
	4 - Mild/Mod	derate	Conju	nctivitis		Ocular Disch	arge		20 - Pe	techia	l Pain /		** Ict	eric lun	nbar and	dears	
	5 - Severe Co	onjunc	tivitis			13 - Vomitin	g		Ecchyr	notic			***-	moribur	nd and e	uthani	zatio
				NO Clinic	al signs ob	served in any	group after 16DPC		22 - De	eath			Ecchymotic ***- moribund and euthanizat 22 - Death DPC – Days post challenge				

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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	Puppies were observed for 21 days after challenge for clinical
challenge	signs.
Results	The study was considered satisfactory by the reduction in
	clinical signs and virus shedding in the vaccinates when
	compared to the control animals.
	Raw Data:
	Data tables are appended to the end of this summary
	Data tables are appended to the end of this summary
USDA Approval Date	April 3, 1998

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	110Pq12DPq13DPq14DPq15DPq16DPq17DPq18DPq19DPq20DPq																								
	C20D	L				L		L			L		L			L				-					
	C19DP	L				L	-		1				L							-					pava
	18DP	L					-						L							п					s ops
	17DPC																								Isign
	16DPC								1											1				oce	Blank - No Clinical signs observed
	15DPC							1,2	1															7-Inappetance	- No
	4DPC	Г						1	1				Г											7-Inap	Blank
	3DPC	П			П	Г		1,2		Г	П		Г		П	Г			П	1		П	П		
enge	2DPC1	Г			П	Г			1	Г			Г			Г				1			П		<u>></u>
Sal	1DPC1	Г			П	Г		П		Г	П		Г		Г	Г		П	П			П	П		ethar
Post	10DPC	r		1				2,4	1			1								1				gui	6 - depression/lethargy
serve	9DPC	2	2	1	2	1	1	1	1	4	1,2	1									1,2			5 -Retching	9 - depr
ns Ob	8DPC	2	1,2	1	1,2,	1		1	1	4	1	1			1					1	1				Ĭ
CAV2 Clinical Signs Observed Post Challenge	7DPC		1,2	1	1,2,4	1,4		1,2,4,5,6	1	1	1	1,2							1	1	1				
AV2 Cli	6DPC	1,2	1,2	1,2	1,2	1	4	1,2,4	1,6	1	1	1,2						1	1	1	1			zing	hing
8	SDPC	1	1	1	1,2	1		1	1,2		1				1					1	1			3- Sneezing	4 - Coughing
	4DPC	Г					2		1		1	2	Г							1					Ì
	3DPC	Г				Г			1,2				Г			Г								e	
	2DPC	П			П	П		П	1,2	Г	П		Г		П	П			П	1		П	П	scharg	harge
	IDPC	П				Г		П	1		Г		Г			Г				1				lar Di	al Dis
	ODPC 1DPC 2DPC																							1 - Ocular Discharge	2- Nasal Discharge
	Group	Control	Control	Control	Control	Control	SC	SC	SC																
	Dog	1	2	60	4	2	9	7	00	6	10	11	23	24	25	56	27	28	53	30	31	32	33		

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						8	W2 Iso	plation	n fron	Nass	al Swa	ıb San	nples	TCD	CAV2 Isolation from Nasal Swab Samples (TCID ₅₀ /100uL)	न						
Dog	Group	ODPC	1DPC	2DPC	3DPC	4DPC	SDPC	6DPC	7DPC	8DPC 9	9DPC 1	ODPC 1	1DPC 1	2DPC 1	3DPC 14	9DPC 10DPC 11DPC 12DPC 13DPC 14DPC 15DPC 16DPC 17DPC 18DPC 19DPC 20DPC	PC 16DP	C 17DP	18DPC	19DPC		21DPC
1	Control				2	2.5	3.63	3.5	51.83	H	H	H	H	Н	H	H	L	L			Г	
2	Control				2	2.83	3.5	3.83	2.17					Н		51.8	83					
m	Control				51.63	3.5	4.17	3.38							2	2.17						
4	Control					2.63	3.38	4.31	2.35			*1	51.63									≤1.63
2	Control				2.38	2.6	4.38	3.6	52.63													
9	Control				51.83	51.83	4.5	3.63	3.63													
7	Control				≤1.63	2.75	4.5	4.5	£1.83													
00	Control				2.38	2.83	3.63	3.17														
6	Control				51.63	2.83	2.83	4.38												51.83		
10	Control				\$1.63	2.17	3.63	3.5				41	51.63	2.38	2.5 \$1.	.83						
11	Control				≤1.83	2.5	4.5	4.38					VI	51.63	51.83 51	51.63 51.63	53	51.63		51.63		
23	SC												_	_	_							
24	SC		51.6				2.38							Н								
25	SC					\$1.63																
26	SC								2.63													\$1.63
27	SC		≤1.63											VI	51.63							
28	SC										-1	51.63		Н								
29	SC				2	<1.83								VI	£1.63	≥1.(.63					
30	SC																					
31	SC													VI	51.63							
32	SC		51.6			≤1.83	2.63	2.5														
33	SC														H	≤1.63	53					
Blank	Blank - No CAV2 titer detected	titer de	tected	_																		
DPC-	DPC - Days Post Challenge	Challer	90																			

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Study Type	Efficacy
Pertaining to	Borrelia burgdorferi
Study Purpose	To demonstrate effectiveness against Borrelia burgdorferi in dogs.
Product	Two doses were administered subcutaneously (SC) 3 weeks apart.
Administration	
Study Animals	Study I: Eighteen (18) 8-14 week old puppies serologically negative for <i>B. burgdorferi</i> were used in the final study analysis. Animals were randomized into one group of 8 SC vaccinates and one group of 10 controls. Study II: Thirty (30) 8 week old puppies serologically negative for
	B. burgdorferi were used in the final study analysis. Animals were randomized into one group of 20 SC vaccinates and one group of 10 controls.
Challenge	Study I: Four weeks after second vaccination all animals were
Description	challenged with Borrelia burgdorferi.
	Study II: Three weeks after second vaccination all animals were challenged with <i>Borrelia burgdorferi</i> .
Interval observed	Study I: Dogs were observed daily for 90 days after challenge for
after challenge	clinical signs associated with <i>B. burgdorferi</i> .
	Study II: Dogs were observed daily for 126 days after challenge for clinical signs associated with <i>B. burgdorferi</i> .
Results	Dogs were evaluated for clinical arthritis, and the detection of <i>B. burgdorferi</i> in blood, fluids, and tissues. Clinical arthritis was defined as the number of discontinuous occurrence of limp and/or lameness for a specific limb. Blood, synovial fluid, lymph nodes, skin and urine samples were collected for <i>B. burgdorferi</i> isolation and/or detection. Data tables are appended to the end of this summary.
USDA Approval Date	December 6, 1995

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Study I: Arthritic Signs Observed

Dog	Treatment	Stiff	Lame	Limping
16	SC Vaccinate		87	
17	SC Vaccinate			
18	SC Vaccinate			
19	SC Vaccinate			
20	SC Vaccinate	78		
21	SC Vaccinate			
22	SC Vaccinate			
23	SC Vaccinate			

Dog	Treatment	Stiff	Lame	Limping
24	Control	59, 61, 87		86
25	Control	52, 62, 64, 65, 70, 71, 72, 73, 74, 75, 87	61, 77, 78	79, 80, 85
26	Control	74, 75	78, 79	80
27	Control	63, 64, 87		
28	Control	49		
29	Control	54, 58, 64, 76		
30	Control	59,78, 80		65, 69, 70, 71, 72, 73, 75, 76, 77, 79, 87
31	Control	41, 52, 57, 59, 60, 61		58, 75, 90
32	Control	50 , 55, 56, 58, 62, 70, 76	58, 59, 60, 61, 69, 73, 75, 77, 78, 85	52, 54, 56, 57, 58, 59, 60, 62, 65, 66, 68, 70, 71, 72, 74, 79, 80, 84, 86, 87, 90
33	Control	38, 41, 42,43, 45, 50, 63, 65, 66, 69, 71, 84	54, 58, 59, 60, 61, 62, 72, 73, 76, 77, 79	38,41,49,52,53, 55, 56, 57, 65, 66, 68, 69, 70, 74, 75, 78, 80, 86, 87, 90

Number - represents the day post challenge the clinical sign was observed

Blank - No signs observed

Clinical arthritis was defined as the number of discontinuous occurrence of limp and/or lameness for a specific limb

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Study I: Detection of B Burgdorferi (Blood)

					. 0				
Dog	Treatment	9DPC	13DPC	20DPC	24DPC	31DPC	34DPC	35DPC	38DPC
16	SC Vaccinate								
17	SC Vaccinate								
18	SC Vaccinate								
19	SC Vaccinate								
20	SC Vaccinate								
21	SC Vaccinate								
22	SC Vaccinate								
23	SC Vaccinate								

Dog	Treatment	9DPC	13DPC	20DPC	24DPC	31DPC	34DPC	35DPC	38DPC
24	Control							+	
25	Control								
26	Control								
27	Control								
28	Control	+		+		+			+
29	Control					+			
30	Control								
31	Control				+		+		
32	Control		+						
33	Control						+		

^{*}Samples were collected periodically from -1DPC through 90DPC, only dates with positive detection are listed. DPC is day post challenge.

Blank - Negative for Borrelia Detection

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[&]quot;+" - Positive for Borrelia Detection

Study I: Detection of B Burgdorferi (Tissues and Fluid) at 90DPC

Dog	Treatment	Lymph Nodes	Synovial Fluid	Skin	Urine
16	SC Vaccinate				
17	SC Vaccinate		+		
18	SC Vaccinate				
19	SC Vaccinate		+		
20	SC Vaccinate	+			
21	SC Vaccinate	+			
22	SC Vaccinate				
23	SC Vaccinate				

Dog	Treatment	Lymph Nodes	Synovial Fluid	Skin	Urine
24	Control			+	
25	Control		+	+	
26	Control	+		+	no sample
27	Control		+		
28	Control		+		+
29	Control		+	+	
30	Control	+			+
31	Control		+	+	+
32	Control		+		
33	Control			+	

DPC is day post challenge

Blank - Negative for Borrelia Detection

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[&]quot;+" - Positive for Borrelia Detection

Study II: Arthritic Signs Observed

Dog	Treatment	Stiff	Lame	Limping
1	SC Vaccinate			
2	SC Vaccinate			
3	SC Vaccinate	54, 77, 95		
4	SC Vaccinate			
5	SC Vaccinate	41, 55, 56, 58, 112		
6	SC Vaccinate			
7	SC Vaccinate	104		
8	SC Vaccinate			
9	SC Vaccinate			
10	SC Vaccinate			
11	SC Vaccinate	95 <i>,</i> 100		28, 98, 99
12	SC Vaccinate		41	
13	SC Vaccinate	98		
14	SC Vaccinate	90		
15	SC Vaccinate	80		84
16	SC Vaccinate	42		76
17	SC Vaccinate			
18	SC Vaccinate			
19	SC Vaccinate	120		
20	SC Vaccinate	44, 45, 57	41, 52, 54	77, 79, 91, 95, 104

Dog	Treatment	Stiff	Lame	Limping
21	Control	30, 50, 53, 56, 58, 63, 95		78
22	Control			
23	Control	63, 65, 93, 94, 106		43, 55, 100
24	Control	65, 82		
25	Control	38, 62, 63, 75, 98, 99, 100, 103, 106		104
26	Control	56, 71, 78, 93, 99,	59, 60, 61, 72, 73, 74, 75, 80, 81, 82, 83, 89, 90, 103, 104, 105, 106, 107, 108, 120, 121, 122, 125, 126	76, 77, 84, 85, 98, 109, 110, 115
27	Control	51, 79, 103		
28	Control	57, 105	105, 125	124
29	Control			
30	Control	104	76, 77, 126	75, 78, 82, 90, 101

 $\label{lem:number-represents} \mbox{Number-represents the day post challenge the clinical sign was observed}$

Blank - No signs observed

Clinical arthritis was defined as the number of discontinuous occurrence of limp and/or lameness for a specific limb

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Study II: Detection of B Burgdorferi (Blood)

		1							Study II: Detection of B Burgdorieri (Blood)										
Dog	Treatment	30DPC	34DPC	35DPC	36DPC	37DPC	41DPC	43DPC	44DPC	76DPC	103DPC								
1	SC Vaccinate																		
2	SC Vaccinate																		
3	SC Vaccinate																		
4	SC Vaccinate																		
5	SC Vaccinate																		
6	SC Vaccinate																		
7	SC Vaccinate																		
8	SC Vaccinate					+													
9	SC Vaccinate																		
10	SC Vaccinate																		
11	SC Vaccinate																		
12	SC Vaccinate																		
13	SC Vaccinate																		
14	SC Vaccinate																		
15	SC Vaccinate																		
16	SC Vaccinate																		
17	SC Vaccinate																		
18	SC Vaccinate																		
19	SC Vaccinate																		
20	SC Vaccinate																		

Dog	Treatment	30DPC	34DPC	35DPC	36DPC	37DPC	41DPC	43DPC	44DPC	76DPC	103DPC
21	Control									+	
22	Control										
23	Control										
24	Control		+	+	+	+	+		+		
25	Control	+	+								
26	Control					+	+	+			+
27	Control										
28	Control										
29	Control										
30	Control										

^{*}Samples were collected periodically from -1DPC through 126DPC, only dates with positive detection are listed. DPC is day post challenge.

Blank - Negative for Borrelia Detection

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[&]quot;+" - Positive for Borrelia Detection

Study II: Detection of B Burgdorferi (Tissues and Fluid) at 126DPC

Dog	Treatment	Lymph Nodes	Synovial Fluid	Skin	Urine
1	SC Vaccinate	+			
2	SC Vaccinate	+			
3	SC Vaccinate		+		+
4	SC Vaccinate	+			
5	SC Vaccinate	+			+
6	SC Vaccinate				
7	SC Vaccinate	+			
8	SC Vaccinate	+		+	
9	SC Vaccinate				
10	SC Vaccinate				
11	SC Vaccinate				+
12	SC Vaccinate		+		+
13	SC Vaccinate	+			
14	SC Vaccinate	+	+	+	
15	SC Vaccinate	+			+
16	SC Vaccinate		+		+
17	SC Vaccinate	+	+	+	
18	SC Vaccinate		+		
19	SC Vaccinate				
20	SC Vaccinate	+		+	

Dog	Treatment	Lymph Nodes	Synovial Fluid	Skin	Urine
21	Control	+	+		
22	Control	+	+	+	
23	Control		+		
24	Control		+	+	+
25	Control	+	+	+	+
26	Control	+	+	+	+
27	Control	+	+		
28	Control	+	+	+	+
29	Control	+	+	+	
30	Control	+			

DPC is day post challenge

"+" - Positive for Borrelia Detection

Blank - Negative for Borrelia Detection

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Study Type	Efficacy
Pertaining to	Borrelia burgdorferi
Study Purpose	To demonstrate effectiveness against <i>Borrelia burgdoferi</i> for one year duration of immunity.
Product Administration	Two doses were administered subcutaneously (SC) 3 to 4 weeks apart.
Study Animals	Study I: Twenty-four (24) dogs serologically negative for <i>B</i> . burgdorferi were used in the final study analysis. Animals were randomized into one group of 12 SC vaccinates and one group of 12 controls. Study II: Sixteen (16) dogs serologically negative for <i>B</i> . burgdorferi were used in the study. Animals were randomized into one group of 5 SC vaccinates, and one group of 11 controls.
Challenge Description	One year after second vaccination all animals were challenged with <i>Borrelia burgdorferi</i> .
Interval observed after challenge	Dogs were observed for 5 months after challenge.
Results	Dogs were evaluated for <i>B. burgdorferi</i> disease. Clinical disease was evaluated by clinical arthritis, the isolation of <i>B. burgdorferi</i> in skin, and detection of Borrelia infection by antibody profile. Clinical arthritis was defined as the number of discontinuous occurrence of limp and/or lameness for a specific limb. Results: Study I 10/12 (83%) - Controls positive for <i>B. burgdorferi</i> disease 2/12 (17%) - SC Vaccinates positive for <i>B. burgdorferi</i> disease Data tables are appended to the end of this summary. No animals (vaccinates or controls) were observed with clinical arthritis in this study. Study II 10/11 (91%) - Controls positive for <i>B. burgdorferi</i> disease 1/5 (20%) - SC Vaccinates positive for <i>B. burgdorferi</i> disease Data tables are appended to the end of this summary. Only one control animal was observed with clinical arthritis in this study. Dog #13 (control) was observed to be lame on 134DPC. All other animals were negative for clinical arthritis.
USDA Approval Date	January 2, 1997

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Study I Isolation of $B.\ Burgdorferi$ in Skin Samples

Animal	Treatment Group	28DPC*	63DPC	91DPC	118DPC
1	SC Vaccinate	-	+	-	+
2	SC Vaccinate	-	-	-	+
3	SC Vaccinate	-	-	-	-
4	SC Vaccinate	-	-	-	-
5	SC Vaccinate	-	-	-	-
6	SC Vaccinate	-	-	-	-
7	SC Vaccinate	-	-	-	-
8	SC Vaccinate	-	-	-	-
9	SC Vaccinate	-	-	-	-
10	SC Vaccinate	-	-	-	-
11	SC Vaccinate	-	-	-	-
12	SC Vaccinate	-	-	-	-
13	Control	-	-	-	-
14	Control	-	-	+	+
15	Control	-	+	-	+
16	Control	-	-	-	+
17	Control	-	+	+	-
18	Control	-	-	+	-
19	Control	-	+	+	+
20	Control	-	+	+	+
21	Control	-	-	-	-
22	Control		+	+	-
23	Control	-	+	+	+
24	Control	+	+	+	-

[&]quot;+" - Positive for Borrelia Detection

DPC is day post challenge

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[&]quot; - " - Negative for Borrelia Detection

Study I Detection of Borrelia infection by serum antibody profile.

Animal	Treatment Group	-1DPC	28DPC	63DPC	89DPC	118DPC	146DPC
1	SC Vaccinate	-	-	-	+	+	+
2	SC Vaccinate	-	-	+	+	+	+
3	SC Vaccinate	-	-	-	-	-	-
4	SC Vaccinate	-	-	-	-	-	-
5	SC Vaccinate	-	-	-	-	-	-
6	SC Vaccinate	-	-	-	=	-	-
7	SC Vaccinate	-	-	-	-	-	-
8	SC Vaccinate	-	-	-	-	-	-
9	SC Vaccinate	-	-	-	-	-	-
10	SC Vaccinate	-	1	-	-	-	-
11	SC Vaccinate	-	-	-	-	-	-
12	SC Vaccinate	-	ı	-	ı	ı	-
13	Control	-	-	-	-	-	-
14	Control	-	-	+	+	+	+
15	Control	-	-	+	+	+	+
16	Control	-	-	-	-	+	+
17	Control	-	-	-	+	+	+
18	Control	-	-	+	+	+	+
19	Control	-	ı	+	+	+	+
20	Control	-	-	+	+	+	+
21	Control	-	-	-	-	-	-
22	Control	-	-	+	+	+	+
23	Control	-	-	+	+	+	+
24	Control	-	-	+	+	+	+

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[&]quot;+" - Antibody positive for presence of *B. burgdorferi* infection " - " -Antibody negative for presence of *B. burgdorferi* infection DPC is day post challenge

Study II Isolation of B. burgdorferi in Skin Samples

Animal	Treatment Group	36DPC	63DPC	91DPC	118DPC	152DPC
1	SC Vaccinate	-	-	-	-	-
2	SC Vaccinate	-	-	-	-	-
3	SC Vaccinate	-	-	-	-	-
4	SC Vaccinate	ı	-	1	+	-
5	SC Vaccinate	ı	-	ı	ı	-
6	Control	-	-	+	+	-
7	Control	-	-	-	-	-
8	Control	+	-	+	+	-
9	Control	+	-	+	+	+
10	Control	+	+	-	+	-
11	Control	ı	-	+	1	-
12	Control	+	-	+	1	-
13	Control	+	+	-	+	-
14	Control	+	-	+	+	+
15	Control	-	-	+	+	-
16	Control	+	-	+	-	-

[&]quot;+" - Positive for Borrelia Detection

DPC is day post challenge

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[&]quot; - " - Negative for Borrelia Detection

Study II Detection of Borrelia infection by serum antibody profile.

Animal	Treatment Group	0DPC	34DPC	62DPC	90DPC	117DPC	152DPC
1	SC Vaccinate	-	-	-	-	-	-
2	SC Vaccinate	-	-	-	-	•	-
3	SC Vaccinate	ı	ı	-	-	ı	-
4	SC Vaccinate	-	-	+	+	+	+
5	SC Vaccinate	-	=	-	-	-	-
6	Control	-	=	+	+	+	+
7	Control	-	=	-	-	-	-
8	Control	-	=	+	+	+	+
9	Control	-	П	-	+	+	+
10	Control	-	+	+	+	+	+
11	Control	-	=	+	+	+	+
12	Control	-	=	+	+	+	+
13	Control	=	=	+	+	+	+
14	Control	-	=	+	+	+	+
15	Control	-	=	-	+	+	+
16	Control	-	=	-	+	+	+

[&]quot;+" - Antibody positive for presence of B. burgdorferi infection

DPC is day post challenge

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[&]quot; - " - Antibody negative for presence of B. burgdorferi infection

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

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Study Type	Efficacy
Pertaining to	Leptospira canicola
Study Purpose	To demonstrate effectiveness against <i>Leptospira canicola</i> in 6
	week old dogs.
Product Administration	Two doses were administered subcutaneously (SC) 3 weeks
	apart.
Study Animals	Twenty-three (23) 6 week old puppies serologically negative for
	Leptospira were randomized into one group of 11 SC vaccinates
	and one group of 12 controls.
Challenge Description	Twenty-one (21) days after second vaccination all animals were
	challenged with <i>Leptospira canicola</i> organisms.
Interval observed after	Dogs were observed daily for 21 days after challenge for clinical
challenge	signs associated with L. canicola. Blood samples were collected
	through 14 days after challenge.
Results	Efficacy was determined by comparing vaccinates versus
	controls in clinical signs, thrombocytopenia, and leukopenia.
	A dog was considered to have thrombocytopenia if the platelet
	count dropped below 200 k/µL and the count was less than 50%
	of the baseline value.
	of the buseline value.
	A dog was considered to have leukopenia if the platelet count
	dropped below 6 $k/\mu L$ and the count was less than 50% of the
	baseline value.
	Data tables are appended to the end of this summary.
USDA Approval Date	April 3, 1998

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		100PC 110PC 120PC 130PC 140PC 150PC 160PC 170PC 180PC 190PC 200PC 210PC		9	BJ																
		C 19DP			8										збе						
		C 18DP				9									DPC = Day post-challenge						
		PC 17DF							AG						post-c						
		PC 16D				9							Ξ		Day 1						
		PC 15D			A	AG			A						PC =						
		PC 14D							A					[
		PC 13D																			
92		DPC 12D																			
hallen		DPC 111				А															
Post C		Г				_															
erved		9DPC									9									served	
Signs Obs	SC Vaccinates	8DPC													3.0-103.9°F)	4.0-104.9°F)	5.0-105.9°F)			nical signs ob	
ola Clinical	SC	7DPC									9				N1 - Fever (103.0-103.9°F)	N2 - Fever (104.0-104.9°F)	N3 - Fever (105.0-105.9°F)	N4 - <99.6°F	P - Death	Blank - no clinical signs observed	
Leptospira canicola Clinical Signs Observed Post Challenge		9DPC				G						А							-		
Lept		SDPC									9	9			harge Mucoid	harge Serous	arge Mucoid	J - Diarrhea Mild (loose stool)	K - Diarrhea Severe (bloody stool)	a	
		4DPC						9	Y		9				G - Ocular Discharge Mucoid	H - Nasal Discharge Serous	I - Nasal Discharge Mucoid	J - Diarrhea Mi	K - Diarrhea Se	L - Bloody Urine	M - Icterus
		3DPC						9				9									
		2DPC					9				G	AD					ing	ethargy	E1 - Conjunctivitis Mild/Moderate	Severe	F- Ocular Discharge Serous
		1DPC		А	A	0	0					A			ance	P0	Breath	ssion/Le	nctivitis	nctivitis	Dischar
		ODPC				g			9		g	g			A-inappetance	B-Vomiting	C-Labored Breathing	D - Depression/Lethargy	E1 - Conju	E2 - Conjunctivitis Severe	F- Ocular
		Dog	12	13	14	15	16	17	18	19	20	21	22				_	_			

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		20DPC 21DPC				8																
		100PC 110PC 120PC 130PC 140PC 150PC 160PC 170PC 180PC 190PC 200PC 210PC											9			DPC = Day post-challenge						
		C 17DPC					A,G						A,G			ost-ch						
		PC 16DP								9 9			1			Дау р						
		DPC 150			G		A			_			1'9	Н)PC=						
		3DPC 14		Ь				Ь	Ь			Ь		Н	[
		12DPC 1			0	Đ'C				9	_		9	G,K								
enge		11DPC	Ь		A,D,N1	9							9	G,K								
t Chall		10DPC											A,K	A,K								
erved Pos		9DPC			O	A,D							A,D,G,K,L	A,D,G,K,L							perved	
Signs Obs	Controls	8DPC			A	A,D,K				G,K			A,D,G,K,L	A,D,G,L,N1		3.0-103.9°F)	4.0-104.9°F)	5.0-105.9°F)			nical signs ol	
ola Clinical)	7DPC		C,D,G,L,N4	A,G	A,G,K	A,D,G			9			A,D,G,K,L	A,D,K,L,N1		N1 - Fever (103.0-103.9°F)	N2 - Fever (104.0-104.9°F)	N3 - Fever (105.0-105.9°F)	N4 - <99.6°F	P - Death	Blank - no clinical signs observed	
Leptospira canicola Clinical Signs Observed Post Challenge		6DPC		A,D,K	A,K	A,D,J	A,K	A,D,E2,M,N4	A,D,E1,K,L,M,N4	A,D,G,K		A,D,G,K,L,M,N4	A,D,G,K,L	A,D,G,K,L								
Lep		SDPC		A,D,G		O	A,N1	A,D,G,K,L,M,N4	D,G,K,L,N4	G,K	D,G,K,L,N4	D,K,L	A,B,J	9		harge Mucoid	arge Serous	arge Mucoid	J - Diarrhea Mild (loose stool)	vere (bloody stool)	a.	
		4DPC	A,D,K,M,N4	A,D,G,J	9	9	А	A,G,L	A,B,D,G,L		B,D,K,L	1′9	A,G			G - Ocular Discharge Mucoid	H - Nasal Discharge Serous	I - Nasal Discharge Mucoid	J - Diarrhea Mi	K - Diarrhea Severe (bl	L - Bloody Urine	M - Icterus
		3DPC			В	D,G,N1	А	A	J,K		G,K	9	A,G,N1	A,G,N2								
		2DPC		D,G,N3	N2	D,G,N1	N1	GN2	D,N2	N2	N2	N1	G,N2	A,N1				ju Bu	ethargy	E1 - Conjunctivitis Mild/Moderate	Severe	F- Ocular Discharge Serous
		1DPC				A,G		A		9			9			tance	8	d Breath	ssion/L	ınctivitis	ınctiviti	Dischar
		0DPC									Ŧ		9			A-inappetance	B-Vomiting	C-Labored Breathing	D - Depression/Lethargy	:1-Conju	E2 - Conjunctivitis Severe	F-Ocular
		Dog	23	24	25	26	27	28	29	30	31	32	33	34		_			_	_	_	

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14DPC 16.6 10.5 12.3 17.6 11.5 13.4 21.7 15.7 9.4 12.7 9.1 13DPC 19.6 23.2 10.2 10.8 17.2 12.3 9.9 9.7 14.7 9.7 11 12DPC 17.2 11.7 13.2 10.2 10.3 10.1 9.3 14 9.2 7.3 9.2 11DPC 11.6 15.3 16.5 10.2 10.7 12.7 13.1 9.3 9.5 8.8 13 10DPC 19.3 11.3 11.7 16.9 8.8 8.5 89 7.7 9.1 Leptospira canicola White Blood Cell Count Post Challenge 10.4 14.9 9DPC 19.4 19.3 11.4 11.7 8.5 7.3 9.3 8.2 9.7 11.8 11.8 10.5 8DPC 16.5 19.2 11.4 20.7 9.8 9.3 6.4 8.3 7DPC 12.5 20.7 12.5 17.4 13.1 9.4 9.7 7.5 9.2 13.4 7.3 13.6 12.2 10.2 13.2 13.9 60PC 11.7 2 7.2 00 6 11 SDPC 15.5 11.5 10.7 12.7 19.3 10.1 14.1 9.4 9.9 6 00 4DPC 14.6 20.3 10.5 12.2 10.2 7.6 9.5 8.2 8.4 8.4 14 3DPC 12.7 11.8 12.9 15.1 9.6 7.6 10.1 12.1 17 9.1 9.1 2DPC 12.3 12.8 10.6 10.7 15.1 9.6 9.3 9.5 9.5 9.4 00 1DPC 25.8 19.8 15.6 12.4 13.2 11.4 15.8 10.5 89 16.1 8.4 (Avg -2DPC, Baseline -1DPC, 0DPC) 22.1 12.3 21.7 13.3 14.3 8.9 11.2 10.2 14 # 11 Dog 12 13 14 15 16 17 18 19 2 22 21

DPC = Day post-challenge. Values reported as $k/\mu L$.

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		14DPC			21.9	13.9	13.3			12.2			16.9	20.2
		13DPC			29.4	12.7	11.5			16.7			17.4	15.9
		12DPC			26.2	11.5	15			12.69			26.3	15.7
		11DPC			36.7	9.6	13.9			9.2			31.5	10.9
		10DPC			36.6	16.6	11.3			11.4			20.5	15.3
Challenge		9DPC			28.1	13.8	7.9			8.7			22.8	17.3
unt Post		8DPC			26	11.7	16.2			10.4			22.8	12.6
od Cell Co	slo.	7DPC		20.5	17		21			11.1			13	12
White Blo	Controls	9DPC		14.6	13.6	8	19.4	13.2	17.5	10.6		15.8	8.7	9
canicola \		5DPC		15.6	12.6	6.7	8.6	19.4	5.3	7.9	10.3	9.9	4.4	3.8
Leptospira canicola White Blood Cell Count Post Challenge		4DPC	21.7	11.5	10	5.7	5.2	7	5	6.1	9	9	5.3	5.6
ľ		ЗОРС	7.4	6.1	8.3	5.6	4.1	3.9	4.2	3.2	4	5.3	2.6	3.4
		2DPC	14.2	16.7	13	9.6	5.5	6.4	7.8	9.5	6.4	11.5	6.1	10.1
		1DPC	21.7	20	11.3	7.9	8.9	18.4	19.4	11.9	10.6	12.2	17.5	9.6
		Baseline (Avg -2DPC, -1DPC, 0DPC)	18.3	16.1	17.1	6	10.4	9.6	12.2	9.5	8.9	11.9	11.8	7
		Dog	23	24	25	26	27	28	29	30	31	32	33	34

DPC = Day post-challenge. Values reported as $k/\mu L$.

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	14DPC	470	467	640	461	390	278	572	524	469	583	593
	13DPC	511	510	802	463	399	257	554	516	464	474	495
	12DPC	483	550	508	438	428	232	406	418	462	429	497
	11DPC	381	616	268	560	302	261	480	414	601	521	200
	10DPC	512	501	267	482	519	270	405	381	493	501	492
	9DPC	631	470	695	497	512	288	483	476	662	581	297
	8DPC	478	565	693	576	655	314	463	379	704	650	473
inates	7DPC	582	636	604	633	558	351	247	375	206	514	469
SC Vaco	бррс	531	467	497	612	555	389	542	376	538	441	517
	5DPC	512	539	536	503	492	329	453	375	523	469	576
	4DPC	473	576	444	421	456	324	398	403	483	447	478
	3DPC	452	573	205	543	452	311	381	324	530	476	581
	2DPC	480	559	452	381	409	247	356	353	497	354	455
	1DPC	538	679	571	407	377	243	331	330	494	332	413
	Baseline (Avg -2DPC, -1DPC, 0DPC)	444.3	551.3	473.3	459.7	477.3	318	425.7	348.7	555.3	378.3	469.3
	Dog	12	13	14	15	16	17	18	19	20	21	22
	SC Vaccinates	Baseline (Avg -2DPC) -1DPC 2DPC 3DPC 4DPC 5DPC 6DPC 7DPC 8DPC 9DPC 11DPC 11DPC 13DPC 13DPC	Baseline (Awg-2DPC, 1DPC) 1DPC (Awg-80PC) 3DPC (AMG-80PC) 5DPC (AMG-80PC) 7DPC (AMG-80PC) 8DPC (AMG-80PC) 478 (AMG-80PC) 478 (AMG-80MC) 478 (AMG-80MC)	Baseline (Avg -2DPC, -1DPC, -1DPC) 1DPC (Avg -2DPC, -1DPC, -1DPC) 1DPC (Avg -2DPC, -1DPC, -1DPC, -1DPC) 5DPC (Avg -2DPC, -1DPC, -1DPC, -1DPC, -1DPC) 3DPC (Avg -2DPC, -1DPC, -1DP	Baseline (Avg -2DPC) -1DPC, ODPC) 2DPC -1DPC, ODPC) 5DPC -1DPC, ODPC) 5DPC -1DPC, ODPC) 7DPC -1DPC, ODPC) 8DPC -1DPC, ODPC 478 -10 -10 -10 -10 -10 -10 -10 -10 -10 -10	Baseline (Avg -2DPC, 1DPC) 2DPC (Avg -2DPC, 1DPC) 5DPC (Avg -2DPC, 1DPC) 5DPC (Avg -2DPC, 1DPC) 3DPC (Avg -2DPC, 1DPC, 1DPC) 3DPC (Avg -2DPC, 1DPC, 1DPC) 3DPC (Avg -2DPC, 1DPC, 1DPC, 1DPC, 1DPC) 3DPC (Avg -2DPC, 1DPC,	Baseline (Avg - 2DPC, -1DPC) 3DPC 4DPC (AVR - 2DPC, -1DPC) 5DPC (AVR - 2DPC, -1DPC, -1DPC) 5DPC (AVR - 2DPC, -1DPC, -1DPC) 5DPC (AVR - 2DPC, -1DPC, -1DPC, -1DPC, -1DPC) 5DPC (AVR - 2DPC, -1DPC, -1DPC	Baseline (Avg-2DPC, -1DPC) 1DPC (Avg-2DPC, -1DPC, -1DPC) 1DPC (Avg-2DPC, -1DPC, -1DPC	Baseline (Avg-2DPC, -1DPC, -1DPC) 1DPC (Avg-2DPC, -1DPC, -1DPC) 1DPC (Avg-2DPC, -1DPC, -1DPC	Baseline (Avg - 2DPC) SC Vaccinates 444.3 538 480 452 473 512 582 478 655 497 667 678 678 678 679 679 679 679 679 110 PC <	SC Vaccinates Avg - 2DPC	Baseline (Awg-2DPC, 1DPC -1DPC, 1DPC, 1DPC -1DPC, 1DPC, 1DPC -1DPC, 1DPC, 1DPC

DPC = Day post-challenge. Values reported as $k/\mu L$.

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					Leptos	pira canic	Leptospira canicola Platelet Counts Post Challenge	et Counts	s Post Cha	llenge					
							Controls	rols							
Dog	Baseline (Avg2DPC, -1DPC, 0DPC)	1DPC	2DPC	3DPC	4DPC	5DPC	ЭФО9	7DPC	8DPC	90РС	10DPC	11DPC	12DPC	13DPC	14DPC
23	300	238	148	11	7.7	O	Q	D	O	O	O	O	Q	O	D
24	342	204	161	64.1	40.5	45.3	123	207	D	Q	D	D	Q	D	D
25	519.7	267	213	187	134	117	160	285	497	710	714	823	738	810	717
26	404.7	278	279	196	150	172	194	ND	302	441	721	648	599	590	588
27	482.7	281	225	119	22	49.9	100	157	405	455	492	552	528	428	435
28	242.3	209	60.4	45.9	3.9	11.1	11.3	D	D	D	D	D	Q	D	D
29	529.7	521	305	195	37.6	15.8	42.2	D	D	D	D	D	D	D	D
30	329.3	292	167	107	61.7	81.6	122	242	412	518	697	504	632	596	551
31	432.7	327	150	80.2	38	14	Q	D	D	D	D	D	D	D	D
32	395.7	329	195	103	33.3	14.2	44.1	D	D	D	D	D	D	D	D
33	563.7	409	182	115	67.1	8.5	2.4	11.4	87.1	235	417	744	701	726	714
34	232.7	174	150	64.5	41.6	8.3	6.8	82.8	142	273	310	383	479	475	564
ND= No Data	ata														
D = dead															

DPC = Day post-challenge. Values reported as k/μL.

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Study Type	Efficacy
Pertaining to	Leptospira grippotyphosa
Study Purpose	To demonstrate effectiveness against Leptospira grippotyphosa
	in 6-week-old dogs.
Product Administration	Two doses were administered subcutaneously (SC) 3 weeks
	apart.
Study Animals	Twenty (20) 6-week-old puppies were randomized into one
	group of 10 SC vaccinates and one group of 10 controls.
Challenge Description	Fifteen (15) days after second vaccination all animals were
	challenged with <i>Leptospira grippotyphosa</i> organisms.
Interval observed after	Dogs were observed daily for 21 days after challenge
challenge	
Results	Efficacy was based on the reduction in spirochetemia in
	vaccinates when compared to controls.
	A data table is appended to the end of this summary.
USDA Approval Date	January 12, 1999

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Isolation of Leptospira from Blood Collected from Dogs Post Challenge

						Contro	l Animals						
Dog	0DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1						+							
2					+		+	+					
3				+	+								
4					+	+							
5				+	+	+							
6						+	+	+	+	+	NA	NA	NA
7				+	+	+	+	+	+	NA	NA	NA	NA
8					+	+	+	+	+	+	NA	NA	NA
9				+	+	+	+	+	+	+	NA	NA	NA
10					+	+	+	+	+	+	NA	NA	NA

NA - Animal Dead or euthanized / no sample taken

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^{+ -} Positive for Leptospira

^{*}Leptospira was not isolated in any of the SC vaccinates

Study Type	Efficacy
Pertaining to	Leptospira icterohaemorrhagiae
Study Purpose	To demonstrate effectiveness against <i>Leptospira</i>
	icterohaemorrhagiae in 6 week old dogs.
Product Administration	Two doses were administered subcutaneously (SC) 3 weeks
	apart.
Study Animals	Twenty-two (22) 6 week old puppies serologically negative for
	Leptospira icterohaemorrhagiae were randomized into one
	group of 10 SC vaccinates and one group of 12 controls.
Challenge Description	Twenty-one (21) days after second vaccination all animals were
	challenged with <i>Leptospira icterohaemorrhagiae</i> organisms.
Interval observed after	Dogs were observed daily for 21 days after challenge for clinical
challenge	signs associated with <i>L. icterohaemorrhagiae</i> . Blood samples
	were collected through 14 days after challenge.
Results	Efficacy was determined by comparing vaccinates versus
	controls in clinical signs, thrombocytopenia, and leukopenia.
	A dog was considered to have thrombocytopenia if the platelet
	count dropped below 200 k/µL and the count was less than 50%
	of the baseline value.
	A dog was considered to have leukopenia if the platelet count
	dropped below 6 $k/\mu L$ and the count was less than 50% of the
	baseline value.
	Data tables are appended to the end of this summary.
USDA Approval Date	March 31, 1998

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		2															
		C 21D															
		20DP			ш		ш										
		100PC 11DPC 12DPC 13DPC 15DPC 16DPC 17DPC 18DPC 19DPC 20DPC 21DPC				ш		A									
		18DPC			٥	٥				٥							
		17DPC			П												
		34 0 9T										В					
		15DPC															
		14DPC															
		13DPC			E							E					
		12DPC					٥										
2		11DPC										D					
Challe		10DPC															
rved Post		9DPC														served	
Leptospira Ictero Clinical Signs Observed Post Challenge	SC Vaccinates	8DPC				F	В						ne	.0°F		nical Sign ob:	
	SC	7DPC											K - Bloody Urine	L - Fever >103.0°F	M - Death	Blank - no clinical Sign observed	
ptospira lcte		OPC 6DPC	А			E					E	D				stool)	ol)
, a		SDPC			Q							0	arge Serous	narge Mucoid	id (loose stool)	derate (Watery stool)	J - Diarrhea Severe (bloody stool)
		4DPC											F - Nasal Discharge Serous	G - Nasal Discharge Mucoid	H- Diarrhea Mild (loose	I- Diarrhea Moderate (W	J - Diarrhea Se
		3DPC			ш	ш						0					ъ
		2DPC										0			ethargy	D- Ocular Discharge Serous	E - Ocular Discharge Mucoid
		1DPC					A,E						tance	20	ssion/L	. Discha	· Discha
		ODPC											A-inappetance	B-Vomiting	C - Depression/Lethargy	D- Ocular	E-Oculai
		Dog	11	12	13	14	15	16	17	18	19	20					

DPC = Day post-challenge

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Contain Signature Contain Signature											_									
Controls Controls			21DPC																	
Controls Controls			20DPC																	
Controls Controls			19DPC		п	ш														
Controls Controls			18DPC			П						0		0	8					
Controls Controls			17DPC			E														
Controls Controls			16DPC			E								E						
Controls Controls			15DPC							٥										
Controls Controls			14DPC																	
Controls Controls			13DPC																	
Controls Controls			12DPC			п				ш										
Controls Controls	nge		11DPC								N		M	E						
0DPC 1DPC 2DPC 3DPC 4DPC 5DPC F	Challe		10DPC										_							
0DPC 1DPC 2DPC 3DPC 4DPC 5DPC F	d Post		DPC		8														P	
0DPC 1DPC 2DPC 3DPC 4DPC 5DPC F	Serve		6																observe	
0DPC 1DPC 2DPC 3DPC 4DPC 5DPC F	igns O	ontrols	8DPC							A						ē	J°F		ical Sign	
0DPC 1DPC 2DPC 3DPC 4DPC 5DPC F	nical S	8	2													ody Urin	er >103.0	eath	- no clin	
0DPC 1DPC 2DPC 3DPC 4DPC 5DPC F	ero Cli		07													K - Blo	L - Fev	M - D	Blank	
0DPC 1DPC 2DPC 3DPC 4DPC 5DPC F	ira lct		26	A										A	ш					
0DPC 1DPC 2DPC 3DPC 4DPC 5DPC F	eptosp		9																stool)	(100
00PC 10PC 20PC 30PC	_		26													erous	Aucoid	se stool	(Watery	loody st
00PC 10PC 20PC 30PC			25													harge S	harge I	ool) plii	oderate	evere (b
00PC 10PC 20PC 30PC)PC	L.	F					٥	ľď:		/E			sal Disc	sal Disc	rrhea M	rhea M	rrhea Se
00PC 10PC 20PC L L L L L L L L A-inappetance B-Vomiting C - Depression/Lethargy D- Ocular Discharge Serous E - Ocular Discharge Mucoin			4								A,(1			F - Na	G-Na	H- Dia	I- Dia	J- Dia
			3DPC			_	_			۵	×		ľD	Е					w	.0
			2DPC			_	_			_	L,E	_		1				thargy	ge Serou	ge Muco
																auce	_	sion/Let)ischarg	Discharg
			DPC 1													nappeta	omiting/	Depres:	Ocular L	Ocular L
Dog 21 22 23 33 30 33 31 31 32 32 33 33 34 35 36 36 37 37 37 37 37 37 37 37 37 37 37 37 37																A-i	4	ن	á	ய்
			00	21	22	23	24	25	26	27	28	29	30	31	32					

DPC = Day post-challenge

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		14DPC	6.4	12.3	8.4	9.1	10.9	8.3	7.3	6.4	6.7	8.9
		13DPC	7.2	9.1	7.8	12.8	7.5	8.3	5.7	8.7	8.8	8.1
		12DPC	9.6	6	8.7	10	11.1	10	10.2	5'9	7	7.6
		11DPC	9.7	10.2	6.7	8.6	7.7	9.5	7.1	8.1	8.7	12.6
		10DPC	8.9	1.7	10.6	13.2	10.4	8.7	11.7	6	1.7	12.5
Leptospira ictero White Blood Cell Count Post Challenge		9DPC	8.5	9.8	8.3	8	7.5	7.7	9.2	8	8.2	8.7
ount Post		8DPC	6.4	11.1	9.6	11.8	8	10.1	11.4	7.4	7.5	9.1
od Cell Co	SC Vaccinates	7DPC	6.4	8.2	9.2	7.3	10.2	8.4	9.4	8.4	10.5	6.4
White Blo	SC Vac	9 С	6.4	15.2	8.8	9.3	11.2	9.4	10.5	7.1	6.7	14.4
ra ictero \		SDPC	10.1	12.4	14.2	11.3	8.3	9.1	7.2	7.3	8.7	14.8
Leptospi		4DPC	6.8	9.1	9.1	12.6	8	8.1	7.5	9.9	11.7	11.9
		ЗОРС	7.9	8.9	13.2	8.2	6	8.9	8.1	9.1	11.7	9.1
		2DPC	12.4	10.4	9.6	12.6	8.6	9.5	7.8	10.5	8.4	5.3
		1DPC	7.3	13.9	15.4	9.7	11.4	8.8	7.1	7.7	13.8.	6.6
		Baseline (Avg -2DPC, -1DPC, 0DPC)	7.2	10	9.7	13.4	8.6	9.1	9.1	7.2	9.5	13.1
		Dog	11	12	13	14	15	16	17	18	19	20

DPC = Day post-challenge. Values reported as $k/\mu L$.

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					Leptospir	a ictero V	Vhite Bloo	eptospira ictero White Blood Cell Count Post Challenge	unt Post (Challenge					
							Cont	Controls							
Dog	Baseline (Avg -2DPC, -1DPC, 0DPC)	1DPC	2DPC	зррс	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
21	7.4	9.9	9.6	6.7	8.2	6.2	8.6	6.7	6.5	8.1	10.4	6.4	8.5	6.5	6.2
22	7.4	8.5	9.3	8.2	6.5	7.3	13.4	9.4	7.2	8.2	13.4	10.1	7.7	7.6	9.4
23	9.3	12.2	9.4	11.6	7.1	6	10	7	6.5	7.1	11.9	7	9.6	11	11.8
24	13.7	19.6	10.6	7.8	11.8	15.3	16.7	19.8	16	13.7	19.2	24.9	13.3	24.4	12.3
25	10	13.9	8.5	6.9	9.1	7	10.9	12.8	9.6	10	13.9	9.4	8.3	6	7.1
26	8.4	8.6	9	3.9	11.8	12.2	15.4	11.3	11.8	6	10.2	13.3	8.6	8.9	10.5
27	7.8	7.5	9.4	15.8	14.6	10.7	9.8	7.5	8.6	12.1	8.6	8.3	11.4	7.4	9.5
28	7.8	8.8	6.7	4.5	7.3	7.3	8.8	14.7	10	11.6	11.7	14	8.3	7.8	7.7
29	7.8	6.7	5.8	4.1	26.4					J	D				
30	8.8	7.6	5	7.2	7.8	7.5	7.8	6.2	9.9	8	10.3	10.1	9.9	9.4	9.6
31	11	8.1	8.3	4.2	19					J	0				
32	8.3	9.3	6.2	5	10.7	12.6	10.6	13.5	14.5	9.6	14.1	9.9	10	10.1	9.3
D = dead															

DPC = Day post-challenge. Values reported as $k/\mu L$.

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												-
		14DPC	359	517	349	281	369	294	381	287	352	378
		13DPC	471	461	337	351	290	284	373	391	406	340
		12DPC	536	473	347	263	401	286	498	283	331	325
		11DPC	586	453	415	330	288	258	417	388	383	501
		10DPC	591	487	522	431	388	316	529	406	356	488
allenge		9DPC	442	505	508	331	285	253	436	424	489	358
Leptospira ictero Platelet Counts Post Challenge		8DPC	488	480	416	376	314	281	513	327	378	392
	nates	7DPC	447	435	517	335	400	268	457	419	500	352
Platelet	SC Vaccinates	6DPС	457	645	445	344	435	308	542	393	459	555
ictero		SDPC	299	526	580	374	282	278	214	351	417	515
otospira		4DPC	440	428	424	457	275	264	332	397	529	525
Le		ЗБРС	476	447	260	349	286	217	386	392	552	483
		2DPC	619	456	425	413	297	298	400	269	386	206
		1DPC	432	475	595	258	380	264	407	482	467	412
		Baseline (Avg2DPC, -1DPC, 0DPC)	449.7	518.3	489.3	451.7	357.7	369	473.7	206	477	502.3
		Dog	11	12	13	14	15	16	17	18	19	20

DPC = Day post-challenge. Values reported as $k/\mu L$.

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				Le	ptospira	ictero	Platelet	ptospira ictero Platelet Counts Post Challenge	Post C	allenge					
							Controls	ols							
Dog	Baseline (Avg -2DPC, -1DPC, 0DPC)	1DPC	2DPC	3DPC	4DPC	SDPC	ОВОВС	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
21	534.3	291	315	207	301	341	545	206	529	537	575	434	399	414	410
22	428.7	238	250	168	126	184	261	288	340	412	520	421	369	386	367
23	411.3	374	307	265	289	362	393	361	369	447	546	444	422	583	535
24	344.7	251	130	99.5	116	189	312	497	440	480	618	635	461	658	451
25	566	401	220	146	189	288	483	611	458	466	660	519	427	432	409
26	392	302	213	94.9	84.5	210	361	381	421	444	467	578	513	452	388
27	475.7	399	423	483	413	335	386	437	465	575	469	461	540	372	474
28	411.7	214	93.5	60.5	128	213	307	332	467	612	622	618	495	467	383
29	332	136	101	6.7	11.2					J	D				
30	421.9	204	80.9	53.9	119	231	379	512	549	516	642	494	411	421	427
31	319.3	163	94.4	36.7	11.9					J	D				
32	267	184	55	7.7	88.8	196	257	347	525	430	529	360	337	287	301
D = Dead	pe														

DPC = Day post-challenge. Values reported as $k/\mu L$.

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Study Type	Efficacy
Pertaining to	Leptospira pomona
Study Purpose	To demonstrate effectiveness against <i>Leptospira pomona</i> in 6
	week old dogs.
Product Administration	Two doses were administered subcutaneously (SC) 3 weeks
	apart.
Study Animals	Twenty (20) 6 week old puppies serologically negative for
	Leptospira were randomized into one group of 10 SC vaccinates
	and one group of 10 controls.
Challenge Description	Twenty-five (25) days after second vaccination all animals were
	challenged with <i>Leptospira pomona</i> organisms.
Interval observed after	Dogs were observed daily for 21 days after challenge. Blood
challenge	samples were collected through 14 days after challenge.
Results	Efficacy was based on the reduction in spirochetemia in
	vaccinates when compared to controls.
	A Data table is appended to the end of this summary.
LICDA Annyoval Data	January 12, 1999
USDA Approval Date	January 12, 1999

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Isolation of Leptospira from Blood Collected from Dogs Post Challenge

					<u> </u>										
							Cont	rol Anin	nals						
Dog	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1			+	+	+	+									
2															
3			+	+	+										
4				+	+										
5			+	+	+	+									
6			+	+											
7		+	+	+											
8			+	+	+										
9		+	+	+	+										
10		+		+	+										

DPC= Day post challenge

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^{*}Leptospira was not isolated from blood in any of the SC vaccinates

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	Puppies were observed for 21 days after challenge for clinical
challenge	signs. Blood and nasal swabs were collected during this period.
Results	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.
	Raw Data: Data tables are appended to the end of this summary
USDA Approval Date	March 16, 1998

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CPI Serum Neutralization Antibody Titers

Control Animals

Dog	0DPV1	14DPV1	0DPV2	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

SC Vaccinates

Dog	0DPV1	14DPV1	0DPV2	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

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CPI Virus Isolation from Nasal Swabs

					<u> </u>					sai sw	4.00				
							Co	ontrol	S						
Do	0DP	1DP	2DP	3DP	4DP	5DP	6DP	7DP	8DP	9DP	10DP	11DP	12DP	13DP	14DP
g	С	С	С	С	С	С	С	С	С	С	С	С	С	С	С
1	-	+	+	+	+	+	+	-	-	-	-	-	-	-	-
2	ı	+	+	+	+	+	+	-	-	-	-	-	-	-	1
3	-	+	+	+	+	+	+	-	+	-	-	-	-	-	-
4	-	+	+	+	+	+	+	-	+	-	-	-	-	-	-
5	-	+	+	+	+	+	+	+	-	-	-	-	-	-	-
6	-	+	+	+	+	+	+	+	+	-	-	-	-	-	-
							SC V	accina	ates						
Do	0DP	1DP	2DP	3DP	4DP	5DP	6DP	7DP	8DP	9DP	10DP	11DP	12DP	13DP	14DP
g	С	С	С	С	С	С	С	С	С	С	С	С	С	С	С
20	-	+	+	+	+	+	-	-	-	-	-	-	-	-	1
21	-	+	+	+	+	+	-	-	-	-	-	-	-	-	1
22	-	+	+	+	+	+	-		+	-	-	-	-	-	-
23	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
24	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
25	-	+	+	+	+	+	-	-	+	-	-	-	-	-	-
26	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
27	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
28	-	+	+	+	+	+	+	-	+	-	-	-	-	-	-
29	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
30	-	+	+	+	+	+	-	-	-	-	-	-	-	-	·
31	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
32	1	+	+	+	+	+	-	-	-	-	-	-	-	-	-

[–] means CPI virus was not detected

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⁺ means CPI virus was detected

Study Type	Efficacy											
Pertaining to	Cannie Distemp	er Virus (CDV))									
Study Purpose	To demonstrate	effectiveness ag	gainst CDV									
Product Administration	Two doses were	administered s	ubcutaneously 21	days apart								
Study Animals	randomly sorted group of 6 contr	into one group ols.	pies seronegative f of 11 SC vaccinat	es and one								
Challenge Description	21 days after sec CDV.	cond vaccinatio	n all dogs were cha	allenged with								
Interval observed after	Dogs were observed for 42 days after challenge for clinical signs											
challenge	of CDV.											
Results	The study was so (b)(3) (i-ii)	atisfactory per t	the criteria in 9 CF	R 113.306								
		Mortality	Clinical Signs of CDV Infection									
	SC Vaccinates	0/11 (0%)	0/11 (0%)									
	Controls	5/6 (83%)	6/6 (100%)									
	Raw Data: Data tables are appended to the end of this summary											
USDA Approval Date	April 6, 1998											

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	10DPC	20	20	2,8,10,12	20	10,12	2,8,10,12													
	9DPC	20	20	1,8,10,11,12	2,8,17	2,10,12	2,10,12	31-42DPC	20	20	20	20		20	d ware not	1011 212 1101				
	8DPC	20	8,10,12,14,16,17,18, Euth	8,10,11,14	1,2,8,10,12	10,11	12,2	30DPC	20	20	20	20	10,12	20	Intermittent minor ctool abnormalities observed were not	on abitomination	gils of CDV IIIIection.			
CDV Clinical Signs Observed Post Challenge - Control Dogs	7DPC	10,12,16,17,Euth	14	14	10,12		11,12	28-29DPC	20	20	20	20		20	Intermittent minor sto	menimicent minor sic	collisidered cillingal signs of CDV illiection.			
st Challeng	6DPC	2,12	1,2,10,12	12	10	10,12	2,10,12	27DPC	20	20	20	20	10,12	20						served
bserved Po	SDPC	10	2,10,12	10,12	2,10,12		2,10,12	16DPC-26DPC	20	20	20	20		20		Salivation	rum fits	cular Tics		Blank - No Clinical signs observed
cal Signs O	4DPC	10,11,12	10				2,12	15DPC	20	20	20	20	11,12	20	14 - Vomiting	16 - Excessive Salivation	17 - Chewing gum fits	18 - neuromuscular Tics	20 - death	Blank - No Cli
CDV Clini	3DPC	10,12,18	2,10,12	2,10,12	2,10,12			14DPC	20	20	1,8,9,10,12	20		20						
	2DPC	10,12,18						13DPC	20	20	8,10,11	20	2,11	20	٨	2- Mild/Mod. Ocular Discharge Mucoid				
	1DPC							12DPC	20	20	1,8,10	20		1,2,8,12	ion/Letharg	d. Ocular Di	tion	stool	tool	tool
	ODPC							11DPC	20	20	8,10,12	70	8,10,12,14	1,2,8,10,12	1 - Depression/Lethargy	2- Mild/Moo	8 - Dehydration	10-Mucous stool	11-watery Stool	12-Bloody stool
	Dog	1	2	3	4	5	9	Dog	1	2	3	4	5	9						

DPC – Days post-challenge

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	21DPC	10,12									12							
	20DPC									12	12		peve					
	19DPC			10							11,12	10,12	Intermittent minor stool abnormalities observed	CDV				
	18DPC										11,12		ormaliti	signs of				
	17DPC		14								10,12	10,12	ol abno	linical				
ogs	16DPC												inor sto	dered				
ted D	15DPC												ttent m	were not considered clinical signs of CDV	'n.			
ccina	14DPC												Intermi	were n	infection.			
e - Va	13DPC																	
CDV Clinical Signs Observed Post Challenge - Vaccinated Dogs	12DPC																	p
d Post Chal	11DPC																	Blank - No Clinical signs observed
ved P	10DPC													vation	fits	ar Tics		Isigns
Obser	C 9DPC												90	16 - Excessive Salivation	17 - Chewing gum fits	18 - neuromuscular Tics		Clinica
Signs	PC 8DP	L										Н	14 - Vomiting	Excess	Chewi	neuror	20 - death	nk - No
inical	DPC 7DF	H						27.0				Н	14		17	18	20	Bla
CDV C	SDPC 60	H										Н		Mucoid				
	4DPC						10							charge				
	3DPC												ethargy	lar Dis				
	C 2DPC	L										Н	ssion/L	lod. Ocu	ration	s stool	Stool	stool
	ODPC 10PC 20PC 40PC 50PC 60PC 70PC 80PC 100PC 110PC 120PC 130PC 140PC 150PC 160PC 180PC 190PC 210PC 210PC	H										\parallel	1 - Depression/Lethargy	2- Mild/Mod. Ocular Discharge Mucoid	8 - Dehydration	10-Mucous stool	11-watery Stool	12-Bloody stool
	Dog	18	19	20	21	22	23	24	25	26	27	28	1	2.	00	10	1	-

DPC – Days post-challenge

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		2DPC											П	hed					
		28DPC 29DPC 30DPC 31DPC 32DPC 33DPC 35DPC 35DPC 37DPC 38DPC 39DPC 40DPC 41DPC 42DPC												Intermittent minor stool abnormalities observed	CDV				
		40DPC											12	ormalitie	were not considered clinical signs of CDV				
		39DPC												ool abno	linical				
		38DPC					14							inor sto	dered				
S		37DPC											12	ttent m	ot cons	on.			
Clinical Signs Observed Post Challenge - Vaccinated Dogs		36DPC												Interm	were n	infection.			
inate		35DPC											12						
Vacci		34DPC											12						
- agua		33DPC											12						pava
Challe	notes	32DPC													no		S		Blank - No Clinical signs observed
I Post	SC Vaccinates	31DPC													16 - Excessive Salivation	17 - Chewing gum fits	18 - neuromuscular Tics		ical sig
served		30DPC						12			10			miting	essive 9	g guiwa	uromus	ath	No Clin
ns Ob		29DPC									10		10,12	14 - Vomiting	16 - Exc	17 - Che	18 - ne	20 - death	Blank -
cal Sig		28DPC						10				12							
		27DPC						10			10	10,11,12			Б				
CD		_						10				10,12			e Mucoi				
		25DPC					10,12							N.	scharge				
		24DPC										10,12	10,12	/Lethar	cular D	_			_
		22DPC 23DPC 24DPC 25DPC 26DPC											10,12	1 - Depression/Lethargy	2- Mild/Mod. Ocular Discharge Mucoid	8 - Dehydration	10-Mucous stool	11-watery Stool	12-Bloody stool
		22DPC	11					10				11,12	11	1 - Depr	2- Mild,	8 - Deh	10-Muc	11-wate	12-8100
		Dog	18	19	20	21	22	23	24	25	26	27	28						

 $DPC-Days\ post-challenge$

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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 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	The data were analyzed according to 9CFR 113.317
	Number affected by challenge according to 9CFR 113.317: Vaccinates: 0/17 (0%)
	Controls: 2/4 (50%)
	Raw data: Data table are appended to the end of this summary.
USDA Approval Date	August 31, 2001

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CPV Post Challenge Daily Observations

			_	_		,	_			_	_	_	_	_	_	_	_		_	_	_	_	_		_
	14DPC							14DPC																	
	13DPC							13DPC																	
	12DPC							12DPC																	
	11DPC							11DPC							E										
	10DPC							10DPC			E		O												
	9DРС							9DPC										O							
trols	SDPC		o					SDPC																	
ated Con	7DPC		S	-	-		Vaccinates	7DPC																	
Non-Vaccinated Controls	6DPC	E,H	B,C,H	B,G,H	B,C,D,F,G,H		Vaco	6DPC			Ŧ														
	SDPC			۵	В,Я			SDPC											O						
	4DPC			I				4DPC																	
	3DPC							3DPC																	
	2DPC							2DPC													Q				
	1DPC	۵						1DPC											Q						
	0DPC							0DPC			Q														
	Dog	1	2	က	4			Dog D	1	2	3	4	2	9	7	œ	6	10	11	12	13	14	15	16	17

E - Watery Stool F - Bloody Stool G - Anorexia B - Lethargy C. Dehydration D - Mucous Stool

H - Vomiting I - Death

DPC = Days Post Challenge

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Daily Rectal Temperature (°F)

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

		_			_			_			_						_		_
	14DPC	101.8	102.1	100.8	102.3	101.8	102.0	101.6	101.2	102.1	101.6	102.2	101.9	101.3	101.7	102.3	102.3	101.7	
	13DPC	101.3	101.3	101.4	100.9	101.3	102.7	101.1	101.3	101.8	101.0	102.1	101.8	101.1	100.5	101.7	101.8	101.2	
	12DPC	101.7	101.7	101.3	101.2	101.5	102.5	101.3	101.0	101.4	101.1	101.9	101.4	101.2	101.0	101.3	101.4	101.4	
	11DPC	101.8	101.7	101.0	101.4	101.7	102.4	101.0	101.3	102.3	101.2	102.5	101.6	101.1	100.8	101.4	101.3	101.2	
	10DPC	101.1	101.4	100.9	101.3	101.6	102.3	101.2	101.1	101.7	101.1	101.7	101.3	101.1	101.4	101.2	101.7	101.6	
	9DPC	101.7	101.6	101.2	101.4	101.5	101.8	101.0	101.1	101.3	101.1	102.3	101.2	101.3	100.4	101.8	101.9	101.4	
	SDPC	101.5	101.7	101.4	101.7	101.3	101.5	101.3	101.1	101.5	101.1	102.3	101.0	101.1	100.7	101.4	101.6	101.7	
Vaccinates	7DPC	101.0	101.3	100.5	101.3	101.1	101.4	101.2	101.0	100.9	100.9	101.5	101.5	101.7	100.7	100.7	101.3	101.3	
Ň	6DPC	101.0	101.5	100.6	101.3	101.3	101.1	100.8	100.9	101.1	100.6	101.8	101.3	100.3	101.5	100.8	100.9	100.8	
	SDPC	101.5	101.5	101.1	101.1	101.0	101.6	100.8	101.3	101.0	101.2	102.2	101.8	101.5	101.4	101.4	102.5	101.9	
	4DPC	101.7	101.1	101.3	101.4	101.2	102.0	100.9	101.1	101.2	101.2	102.1	101.4	101.0	101.0	101.6	101.8	101.2	
	3DPC	101.3	101.3	100.8	101.7	101.5	101.5	101.2	101.1	101.0	101.4	101.8	101.5	101.3	101.4	101.0	101.7	102.1	
	2DPC	101.2	101.5	101.0	101.4	101.4	102.1	101.0	101.5	102.1	101.6	10.2	101.4	101.8	101.0	101.1	101.9	102.0	
	1DPC	101.9	100.5	100.5	100.9	101.0	101.9	100.8	100.7	101.6	100.8	101.5	102.2	100.4	101.1	101.2	102.1	101.6	nallenge
	0DPC	101.1	101.1	101.0	100.7	101.0	101.3	100.5	69.7	100.5	101.3	101.3	100.9	6.66	69.7	100.7	100.9	101.8	rs Post CL
	Cat ID	s	9	7	œ	6	10	11	12	13	14	15	16	17	18	19	20	21	DPC = Days Post Challenge

DPC = Days Post Challenge

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Total White Blood Cell Counts (x1000/uL)

	10DPC	10.3	12.9	Na	Na
	9DPC	10.5	9.0	Na	Na
	8DPC	9.7	10.0	Na	Na
	7DPC	9.0	7.5	Na	Na
trols	6DPC	8.2	13.0	13.7	0.3
Non-Vaccinated Controls	5DPC	13.9	12.7	15.6	6.3
ı-Vaccina	4DPC	11.2	17.0	30.2	19.9
Nor	3DPC	11.5	11.7	Na	17.4
	2DPC	13.2	14.4	23.0	17.4
	1DPC	10.7	12.3	18.0	18.4
	0DPC	12.3	6.6	20.6	14.7
	Cat ID	1	2	3	4

	_	_		_	_			_	_		_		_	_			_	_
	10DPC	10.7	10.0	8.4	9.7	7.3	6.6	14.9	10.1	9.5	10.3	23.2	13.1	8.5	8.8	16.2	16.2	14.3
	9DPC	10.3	9.3	10.0	8.4	7.3	12.0	8.8	10.8	13.9	10.0	14.2	12.8	14.4	10.0	17.7	19.6	12.1
	8DPC	8.6	10.3	10.9	8.2	8.2	20.3	18.9	11.2	14.1	11.4	10.3	12.0	11.0	9.4	16.3	18.3	10.1
	7DPC	9.1	8.6	8.9	8.6	8.1	10.2	10.7	12.1	11.5	14.1	10.4	15.4	6.6	9.4	20.3	19.6	14.5
	6DPC	9.18	9.61	8.73	8.40	8.17	8.00	7.71	10.70	11.80	17.10	11.0	12.6	7.8	11.8	17.2	14.1	12.9
Vaccinates	SDPC	12.7	10.1	10.2	9.3	9.3	10.0	8.8	10.4	11.2	14.0	10.9	14.7	12.7	14.9	28.6	28.2	14.4
Vacci	4DPC	10.3	9.3	9.4	9.0	6.7	6.6	9.4	13.9	11.0	20.4	10.6	16.0	9.3	14.7	21.9	18.9	12.8
	3DPC	8.4	11.0	9.1	10.0	10.3	12.3	Na	15.3	15.1	Na	12.6	16.0	Na	14.6	20.0	17.4	15.9
	2DPC	11.8	12.7	9.3	10.2	12.8	15.1	9.8	21.8	16.1	17.6	14.5	16.0	9.1	11.0	27.7	18.7	14.3
	1DPC	11.8	10.2	9.0	10.4	12.8	13.7	11.7	18.5	17.6	21.6	17.6	18.5	10.8	14.8	28.2	21.3	11.6
	0DPC	10.2	11.0	13.5	11.9	12.5	12.7	11.3	27.2	7.8	20.4	16.7	21.6	13.6	12.4	37.0	19.0	16.7
	Cat ID	5	9	7	8	6	10	11	12	13	14	15	16	17	18	19	20	21

DPC = Days Post Challenge

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 \Box

		10DPC	1.5	3.4	NS	NS
		9DPC	2.0	3.5	NS	NS
		SDPC	5.2	4.5	NS	NS
ng Feces		7DPC	5.5	5.4	NS	NS
FAID ₅₀ /r	trols	6DPC	5.8	5.6	NS	6.2
erial (Log	Non-Vaccinated Controls	SDPC	4.2	3.8	5.5	NS
ecal Mat	n-Vaccina	4DPC	2.4	1.5	3.2	3.5
CPV Titer From Fecal Material (Log FAID _{so} /mg Feces)	Noi	3DPC	<1.5	<1.5	<1.5	<1.5
CPV Tite		2DPC	<1.5	<1.5	<1.5	<1.5
		1DPC	<1.5	<1.5	<1.5	<1.5
		0DPC	<1.5	<1.5	<1.5	<1.5
		Cat ID	1	2	3	4

							_			_			_			_		
	10DPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
	9DPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	41.5
	SDPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	415
	7DPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	41.5
	6DPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
Vaccinates	SDPC	NS	<1.5	NS	<1.5	<1.5	NS	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	NS	<1.5
Vacci	4DPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	41.5
	3DPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	41.5
	2DPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	415
	1DPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	4.5
	0DPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	41.5
	Cat ID	5	9	7	8	6	10	11	12	13	14	15	16	17	18	19	20	21

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

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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	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	Puppies were observed for clinical signs daily for 14 days after
challenge	challenge
Results	Dogs were determined affected by the criteria of 9CFR
	113.317(c)(3)(i)
	Number affected:
	Vaccinates: 1/20 (5%)
	Controls: 4/5 (80%)
	Requirements of 9CFR 113.317 (c)(3)(i) were met.
	Raw data:
	Data tables are appended to the end of this summary.
USDA Approval Date	January 31, 2012
OSDIT TIPPIOVAL DATE	Validaty 0.1, 20.12

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1 - Mucous Stool 2-Diarrhea	28	24	23	22	20	18	17	16	15	14	13	10	8	7	6	5	4	3	2	1	Dog ID		27	21	19	1	9	Dog ID	
1 - Mucous Stool 2-Diarrhea (Watery stool)			1										1				1				0DPC							0DPC	
ry stool)																					1DPC							1DPC	
																					2DPC							2DPC	
3-BloodyStool																					3DPC							3DPC	
ly Stool																					4DPC							4DPC	
																					5DPC					1,2,3	1,2,3	5DPC	
Blank - 1																					6DPC	Va			1	1,2,3	1,2,3	6DPC	Non-Vaccinated Controls
Blank - No clinical signs observed																					7DPC	Vaccinates		2,3	1	1,2,3	1,2,3	7DPC	mated Co
l signs ol							1														SDPC			1,3	1	2,3	2,3,4	8DPC	ntrols
oserved							2														9DPC						Na	9DPC	
																		1			10DPC						Na	10DPC	
																					11DPC						Na	11DPC	
																					12DPC						Na	12DPC	
									1											1,3	13DPC						Na	13DPC	-
								1													14DPC						Na	14DPC	

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	28	24	23	22	20	18	17	16	15	14	13	10	8	7	6	5	4	3	2	_	Dog ID		27	21	19	11	9	Dog ID	
DRV4 Davis post first Vessionies	128	4	2	<2	45	16	32	8	23	32	181	128	512	1448	1024	2048	153	54	64	91	-24DPV1		10	2	23	91	724	-24DPV1	
ř	32	11	8	11	11	23	32	11	6	8	6	45	32	6	23	45	64	45	32	32	0DPV1		00	11	64	4	8	0DPV1	
	16	4	1	8	4	19	23	11	2	16	6	64	8	4	23	16	23	23	23	8	7PV1		6	10	23	3	4	7PV1	
ŕ	\$	<2	<2	<2	<2	<2	5	2	<2	2	<2	2	<2	<2	<2	<2	<2	2	<2	<2	28DPV1 (0DPV2)	Vaccinates	٥,	2	<2	<2	<2	28DPV1 (0DPV2)	Non-Vaccinated
	1448	1024	1448	4	724	512	<2	<2	512	<2	45	<2	<2	1024	<2	45	724	1024	362	1024	41DPV1	ates	٥.	2	<2	<2	<2	41DPV1	d Controls
1000	4096	16384	NO TEST	8192	8192	23170	11585	9767	11585	2896	2048	11585	2896	8192	512	4096	19534	5793	6871	11585	56DPV1		٥.	<2	<2	<2	<2	56DPV1	
	11585	23170	16384	11585	16384	11585	8192	11585	11585	4884	5793	11585	11585	8192	2896	8192	23170	5793	16384	11585	70DPV1		٥	2	2	<2	<2	70DPV1	
0.0.	9767	16384	11585	8192	11585	11585	16384	23170	16384	11585	8192	11585	=>46341	=>23170	9767	23170	=>46341	6871	16384	=>23170	84DPV1 (0DPC)		٥	٥	^2	<2	<2	84DPV1 (0DPC)	

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;						Controls	Controls)		1	
CatID	-2DPC	-1DPC	0DPC	Average	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	_	8DPC
9	1.24	1.20	1.38	1.27	1.71	1.45	0.80	0.30	0.28	0.74	0.27		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
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
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
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
						S	Single Si						
2	3000	1000	0000	Avorago	10BC	2000	vaccinates	ADBC.	2002	200	ZDBC	0	on on one
. i	306	306	274	205	306	3 2 6	2 (2)	3 30	386	3 2	2 57	٠,	304
2 -	2.45	2.50	2.34	2.43	3.32	3.05	3.27	3.03	2.73	3.20	3.23	2	2.92
ω	2.09	2.40	2.34	2.28	2.42	2.46	2.32	1.65	1.73	2.38	2.16	2	.42
4	1.10	1.59	2.46	1.72	3.23	2.45	2.91	2.03	2.75	2.34	2.41	2	2.87
5	0.62	0.96	1.16	0.91	1.23	1.32	1.14	1.26	1.19	1.57	1.49	_	.36
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
7	1.23	1.22	1.18	1.21	1.18	1.51	1.53	1.68	1.52	1.81	0.22	1	1.67
8	2.07	1.89	2.00	1.99	1.81	1.93	1.78	1.52	1.64	2.52	2.23	2	2.51
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
13	1.26	2.25	2.24	1.92	2.43	1.88	2.57	2.39	2.57	3.09	3.22	ω	3.24
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
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
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
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
18	2.06	2.82	2.50	2.46	2.97	2.48	2.62	3.05	3.04	3.98	3.27	2.	2.26
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
22	3.80	3.05	3.35	3.40	3.96	3.18	3.38	3.75	2.36	2.42	3.93	з	3.23
23	0.84	1.46	1.51	1.27	1.63	1.35	1.47	1.45	1.29	1.72	1.53	1	1.44
24	0.97	2.04	2.32	1.78	2.09	2.24	2.67	2.03	2.03	2.70	2.46	2	2.68
2	2 43	2.68	2.15	2.42	2 68	2.89	3.56	3.56	2.52	2.46	3.57	ω	3.61

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					Non-Vacci	Non-Vaccinated Controls	"			
Dog ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC
9	102.0	102.0	102.6	102.9	103.2	104.6	103.2	100.9	Na	ьN
1	102.6	102.9	102.6	102.6	103.1	103.4	102.8	102.2	101.3	101.5
19	102.5	102.8	102.1	102.3	101.9	103.8	102.3	102.4	101.6	102.1
21	102.2	102.3	101.3	101.4	102.0	103.4	102.0	101.8	101.5	101.5
27	102.2	102.1	102.1	102.7	102.5	102.8	103.0	102.4	100.9	101.6
					}					
					Vac	Vaccinates				
Dog ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	OPC6
1	101.9	102.0	101.9	101.9	101.7	102.0	101.5	101.9	101.3	101.6
2	102.7	103.5	103.1	103.1	103.5	102.3	103.1	102.9	102.4	102.6
သ	103.0	103.0	102.5	102.2	102.7	102.7	103.1	103.0	102.1	102.5
4	101.6	102.4	102.3	102.1	102.4	102.1	103.4	102.7	102.1	1.201
5	103.5	103.4	103.2	103.3	103.5	102.6	102.8	103.4	102.8	.03
6	102.7	102.6	101.7	102.8	102.4	102.4	102.8	102.7	102.2	102.4
7	101.7	102.5	102.5	103.3	103.0	103.1	103.1	103.1	102.9	102.6
8	102.7	102.9	102.5	102.4	102.6	102.2	102.2	102.5	101.7	101.2
10	103.1	103.3	102.3	102.8	103.0	102.5	102.2	102.7	102.8	101
13	103.0	102.5	102.8	102.2	103.2	102.6	102.7	103.0	102.4	102.
14	102.3	102.8	102.4	102.4	102.7	102.4	102.6	102.4	102.0	101.9
15	102.5	102.7	102.3	102.0	102.8	102.2	102.4	102.4	101.9	102.
16	101.7	102.5	102.8	101.9	102.5	102.1	102.1	101.9	101.5	101.1
17	101.9	102.8	102.3	102.6	102.7	102.1	102.0	101.9	102.0	101.7
18	102.2	102.5	102.1	101.5	102.3	102.6	102.0	102.0	101.9	101.8
20	102.2	101.9	101.9	102.0	102.2	101.8	101.8	101.9	101.6	101.4
22	102.7	102.9	102.4	101.8	102.8	102.5	102.5	102.8	102.0	102.0
23	102.5	102.8	102.7	102.7	103.2	102.4	102.7	103.1	102.1	102.4
24	103.3	103.1	102.6	102.2	102.5	102.4	102.2	102.2	102.1	101.8
SC	102.2	102.1	102.0	102.4	102.2	102.2	102.0	102.0	101.8	101.5

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Positive For CPV	28	24	23	22	20	18	17	16	15	14	13	10	8	7	6	5	4	3	2	1	CatID		27	21	19	11	9	CatID	
	- 1	s1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	0DPC		s1.5	<u><1.5</u>	≤1.5	≤1.5	≤1.5	0DPC	
>1.5 log ¹⁰ FAID ₅₀ /mL	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.6	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.8	≤1.5	1DPC		≤1.5	≤1.5	≤1.5	≤1.8	≤1.5	1DPC	
	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	2DPC		≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	2DPC	
	≤1.5	≤1.5	<1.5	≤1.5	≤1.5	<1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	3DPC		≤1.5	≤1.8	≤1.5	≤1.5	≤1.5	3DPC	
	≤1.5	≤1.5	<1.5	<1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	4DPC	Vac	≤2.8	4.3	2.5	5.5	≤2.5	4DPC	Co
	≤2.5	<1.5	<1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	5DPC	Vaccinates	5.2	4.7	4.2	7.2	6.6	5DPC	Controls
	≤1.5	<1.5	<1.5	<1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	6DPC		7.4	6.3	7.5	7.5	7.6	6DPC	
	≤2.5	<1.5	s1.5	<1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	7DPC		6.6	6.8	7.6	≥8.5	5.2	7DPC	
	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	5.1≥	≤1.5	≤1.5	≤1.5	8DPC		5.2	≤2.8	4.2	9.8≤	2.6≈	8DPC	
	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	9DPC		≤3.0	4.5	4	≥7.6	Na	9DPC	
	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	10DPC		≤1.5	3.6	≤1.5	6.6	Na	10DPC	

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Study Type	Safety
Pertaining to	Canine Adenovirus Type 2 (CAV-2)
Study Purpose	Development of corneal opacity is not associated with the use of
ų I	this product
Product Administration	
Study Animals	
Challenge Description	
Interval observed after	
challenge	
Results	Study data are not available
1	

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Study Type	Safety						
Pertaining to	All						
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	NA						
Interval observed after	No challenge. Observed for 30 minutes after vaccination and						
challenge	then daily for 2 weeks after each vaccination.						
Results	Frequency of events is appended to the end of this summary.						
USDA Approval Date	November 15, 2002						

Summary of Reactions:

	Puppies up to 6 weeks of age				Dogs > 6 Weeks of Age					
Reaction Type	<24hr	>24hrs	Total Reactions by dose	%	<24hr	>24hrs	Total Reactions by dose	%	Sum of Doses	Reaction Rate
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.

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