

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	45J9.20
True Name	Canine Distemper-Adenovirus Type 2-Coronavirus-Parvovirus Vaccine, Modified Live & Killed Virus, Leptospira Canicola-Grippotyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	ULTRA Duramune DAP + C4L - Elanco US Inc.
Date of Compilation Summary	December 19, 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 Canin	ne Hepatitis Vir	us	
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	` /	into one group	pies, seronegative of 11 SC vaccinat	-
Challenge Description	21 days after sec Infectious Canin		n all dogs were cha us.	allenged with
Interval observed after		served for $\overline{21}$ d	ays after challenge	e for clinical
challenge	signs.			
Results	The study was s (1)(ii) (A)(B)	atisfactory per t	the criteria in 9 CF	R 113.305
		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			

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				Car	nine Infe	ectious He	patitis Clinical Sigr	ıs Obs	serve	d Pos	t Cha	lleng	е					
Dog	Treatment	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC	15DPC	16DP
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						NA					
4	Control				23**	1,3,7	1,3,6,7,17,20,22***	1										
5	Control			23*	3	22	N/A	1										
6	Control			7	7	22	N/A	1										
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/Let	nargy			6 - Serous o	cular discharge		15 - Ex	cessive	Saliva	tion		23 - O	ther			
	3- Dehydrati	ion				7 - Mild/Mo	derate mucopurulent		17 - Ic	teric Gu	ıms			* Icter	ic Luml	oar onl	У	
	4 - Mild/Mo	derate	Conju	nctivitis		Ocular Disch	arge		20 - Pe	etechia	Pain /			** Icte	ric lum	bar an	d ears	
	5 - Severe Co	onjunc	tivitis			13 - Vomitin	g		Ecchyı	notic				***- n	noribun	d and	euthani	zation
				NO Clinic	al signs ob	served in any	group after 16DPC		22 - D	eath				DPC – [Days po	st chall	enge	

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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
USDA Approval Date	April 3, 1998

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	110Pq12DPq13DPq14DPq15DPq16DPq17DPq18DPq19DPq20DPq																								
	C20D	L				L		L			L		L							-					
	C19DP	L				L	-		-				L							-					peve
	18DP	L					-													п					s ops
	17DPC																								Isign
	16DPC								1											1				e	Blank - No Clinical signs observed
	SDPC	Г						1,2	1															7-Inappetance	- No C
	4DPC	Г			П	Г			1	Г	Г		Г						Г					-Inap	Slank
	3DPC1	Г	П		П	Г		1,2		Г	П		Г					П	Г	1		Г	П	7	
enge	2DPC1	Н	Н		Г	Н			1	Г			Г						Г	1		Г	П		Ž.
Chall S	IDPCI	Н	Н		Н	Н		Н		Н	Н		Н						Н			Н	П		6 - depression/lethargy
ost	10DPC 11	Н		1		Н		2,4	1		Н	1	H						Н	1					l/uois
Sed F	-	H	H		H	H	H	2		L	H		H						H			H	Н	5 -Retching	epres
bser	9DPC	2	2	-	2	-	-	-	-	4	1,2	-									1,2			5 -Re	9 - q
o sua	8DPC	2	1,2	1	1,2,	1		1	1	4	1	1			1					1	1				
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 CI	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
ð	SDPC	1	1	1	1,2	1		1	1,2		1				1					1	1			3- Sneezing	4 - Coughing
	4DPC	Г	П		П	Г	2	П	1	Г	-	2	Г						Г	1		Г	П		Ì
	3DPC	Г	П		П	Г	Г	П	1,2	Г	Г		Г			П			Г			Г	П	e u	
	DPC	Г	П		П	Г		П	1,2	Г	П		Г					П	Г	1		Г	П	charg	harge
	DPC 2	Н	Н		П	П		П	1		П		Г						П	1		Г	П	ar Dis	I Disc
	ODPC 1DPC 2DPC	H																						1 - Ocular Discharge	2- Nasal Discharge
	Group	Control	Control	Control	Control	Control	SC	SC	SC																
	Dog	1	2	8	4	2	9	7	00	6	10	11	23	24	25	56	27	28	53	30	31	32	33		

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						8	V2 Iso	platio	n fron	n Nass	al Swa	ab Sar	nples	(TCID)	CAV2 Isolation from Nasal Swab Samples (TCID ₅₀ /100uL)	ul)						
Dog	Group	ODPC	1DPC	2DPC	2DPC 3DPC	4DPC	SDPC	6DPC	7DPC	8DPC 9	9DPC 1	10DPC 1	1DPC 1	2DPC 1	9DPC 10DPC 11DPC 12DPC 14DPC 15DPC 16DPC	DPC 15	DPC 16t	DPC 17DF	C 18DP	170PC 180PC 190PC 200PC 210PC	20DPC	21DPC
1	Control				2	2.5	3.63	3.5	51.83		Г			Н	H	H	H	H	L	L		
2	Control				2	2.83	3.5	3.83	2.17							S	51.83					
က	Control				51.63	3.5	4.17	3.38							2	2.17						
4	Control					2.63	3.38	4.31	2.35				51.63									≤1.63
2	Control				2.38	5.6	4.38	3.6	\$2.63													
9	Control				51.83	≤1.83	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					51.63	2.38	2.5 5	51.83						
11	Control				51.83	2.5	4.5	4.38					41	51.63	51.83	51.63 51	51.63	51.63	9	51.63		
23	SC																					
24	SC		51.6				2.38															
25	SC					51.63																
56	SC								2.63													\$1.63
27	SC		≤1.63											41	51.63							
28	SC											51.63										
53	SC				2	≤1.83								VI	£1.63	Vi	≤1.63					
30	SC																					
31	SC													ΨI	£1.63							
32	SC		51.6			≤1.83	2.63	2.5														
33	SC															Vi	≤1.63					
Blank	Blank - No CAV2 titer detected	titer d	stected																			
DPC-	DPC - Days Post Challenge	Challer	90																			

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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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		21DPC																		
		20DPC		9	8]															
		10DPC 11DPC 12DPC 13DPC 14DPC 15DPC 16DPC 17DPC 18DPC 19DPC 21DPC			8									že						
		18DPC				9								DPC = Day post-challenge						
		17DPC							AG					ost-ch						
		16DPC				9							Ξ)av bo						
		15DPC			А	AG			A					C = I						
		14DPC							A					DP	╚					
		13DPC																		
		C 12DP(
llenge		C 11DP(
st Cha		10DP				A														
erved Po		9DPC									9								pserved	
Signs Obs	SC Vaccinates	8DPC												3.0-103.9°F)	1.0-104.9°F)	3.0-105.9°F)			nical signs o	
Leptospira canicola Clinical Signs Observed Post Challenge	SCV	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	
ospira canic		6DPC				9						А								
Lepto		5DPC									9	9		G - Ocular Discharge Mucoid	H - Nasal Discharge Serous	I - Nasal Discharge Mucoid	J - Diarrhea Mild (loose stool)	evere (bloody stool)	ē	
		4DPC						9	A		9			G - Ocular Dis	H - Nasal Disc	I - Nasal Disch	J - Diarrhea M	K - Diarrhea Severe (b	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	٥	0					A		tance	50	d Breath	ssion/L	ınctiviti	ınctiviti	Dischar
		0DPC				9			9		g	9		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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		PC 21DPC																				
		100PC 110PC 120PC 130PC 140PC 150PC 160PC 170PC 180PC 190PC 210PC				8	A,G						A,G G			DPC = Day post-challenge						
		VC 15DPC 16DP					А			9 9			1′9			C = Day p						
		3DPC 14DF		Ь	9			Ь	۵			Ь			[DI	_					
		12DPC 1			٥	9′0				9	Ь		9	G,K								
allenge		C 11DPC	Ь		A,D,N1	9							9	G,K								
ost Cha													A,K	A,K								
served P		9DPC			Q	A,D							A,D,G,K,L	A,D,G,K,L							pserved	
Signs Ob	Controls	8DPC			A	A,D,K				G,K			A,D,G,K,L	A,D,G,L,N1		3.0-103.9°F)	1.0-104.9°F)	5.0-105.9°F)			ical signs o	
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		Q	A,N1	A,D,G,K,L,M,N4	D,G,K,L,N4	S,K	D,G,K,L,N4	D,K,L	A,B,J	9		harge Mucoid	narge Serous	arge Mucoid	J - Diarrhea Mild (loose stool)	K - Diarrhea Severe (bloody stool)	a.	
		4DPC	A,D,K,M,N4	A,D,G,J	9	9	A	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 Se	L - Bloody Urine	M - Icterus
		3DPC			8	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				ji Bi	ethargy	E1 - Conjunctivitis Mild/Moderate	Severe	F- Ocular Discharge Serous
		1DPC				A,G		A		9			9			etance	20	d Breath	D - Depression/Lethargy	unctivitis	unctiviti	r Dischar
		0DPC									н		9			A-inappetance	B-Vomiting	C-Labored Breathing	D - Depr	E1 - Conj	E2 - Conjunctivitis Severe	F- Ocula
		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 10.1 15.1 9.6 7.6 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 10.5 15.6 12.4 13.2 11.4 15.8 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		90РС			28.1	13.8	7.9			8.7			22.8	17.3
ount Post		8DPC			26	11.7	16.2			10.4			22.8	12.6
od Cell Co	rols	7DPC		20.5	17		21			11.1			13	12
White Blo	Controls	бррс		14.6	13.6	8	19.4	13.2	17.5	10.6		15.8	8.7	9
Leptospira canicola White Blood Cell Count Post Challenge		5DPC		15.6	12.6	6.7	8.6	19.4	5.3	7.9	10.3	9.9	4.4	3.8
eptospira		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	568	260	302	261	480	414	601	521	200
	10DPC	512	501	267	482	519	270	405	381	493	501	492
	9DРС	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	706	514	469
SC Vacc	6DPС	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	505	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, -1DPC, 0DPC) 1DPC and a control of a co	Baseline (Avg -2DPC, -1DPC) 1DPC ODPC) 3DPC AVG	Baseline (Awg -2DPC, -1DPC, -1DPC) 1DPC (Awg -2DPC, -1DPC, -1DPC) 3DPC (AWg -2DPC, -1DPC, -1DPC, -1DPC, -1DPC) 5DPC (AWg -2DPC, -1DPC, -1DPC, -1DPC, -1DPC, -1DPC, -1DPC, -1DPC, -1DPC) 3DPC (AWg -2DPC, -1DPC, -1DP	Baseline (Avg - 2DPC) SC Vacinates -1DPC, -1DPC, DDPC) 1DPC 3DPC 4DPC 5DPC 7DPC 8DPC 478 6DPC 1DPC 1DPC 1DPC 13DPC 13DPC	Baseline (Avg -2DPC)	Baseline (Avg - 2DPC, -1DPC) 3DPC 4DPC (AVR - 2DPC, -1DPC) 5DPC (AVR - 2DPC, -1DPC) 5DPC (AVR - 2DPC, -1DPC) 5DPC (AVR - 2DPC, -1DPC, -1DPC) 5DPC (AVR - 2DPC, -1DPC, -1DPC, -1DPC) 5DPC (AVR - 2DPC, -1DPC, -1DPC, -1DPC, -1DPC) 5DPC (AVR - 2DPC, -1DPC, -1DPC	Baseline (Avg-2DPC, 1DPC) 4.1 1DPC (Avg-2DPC, 1DPC) 4.2 1DPC (Avg-2DPC, 1DPC) 4.2 4DPC (Avg-2DPC, 1DPC, 1DPC, 1DPC, 1DPC) 4.2 4DPC (Avg-2DPC, 1DPC, 1DPC, 1DPC, 1DPC, 1DPC, 1DPC, 1DPC) 4.2 4DPC (Avg-2DPC, 1DPC, 1DPC	Baseline (Avg-2DPC, -1DPC, -1D	Baseline Actorinates SC Vaccinates Avg -2DPC, -1DPC,	SC Vaccinates Awg-2DPC, 1DPC 2DPC 3DPC 4DPC 5DPC 6DPC 7DPC 8DPC 4DPC 4	Baseline (Awg-2DPC, -1DPC) 10PC 3DPC 4DPC 4DPC <th< td=""></th<>

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	Post Cha	llenge					
							Controls	rols							
Dog	Baseline (Avg -2DPC, -1DPC, 0DPC)	1DPC	2DPC	зорс	4DPC	5DPC	ОРС	7DPC	8DPC	90РС	10DPC	11DPC	12DPC	13DPC	14DPC
23	300	238	148	11	7.7	O	O	O	O	O	O	O	Q	O	D
24	342	204	161	1.49	40.5	45.3	123	207	D	Q	D	O	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	55	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	O	Q	Q	D	Q	Q	O	D
29	529.7	521	305	195	37.6	15.8	42.2	D	D	Q	D	O	Q	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	D	D	D	D	D	O	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 $k/\mu L$.

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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.						
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 L. icterohaemorrhagiae. 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 leadronesis if the platelet count
	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.
	baseline value.
	Data tables are appended to the end of this summary.
	Data tables are appended to the end of this summary.
USDA Approval Date	March 31, 1998

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)PC															
		100PC 110PC 120PC 130PC 140PC 150PC 170PC 180PC 190PC 200PC 210PC															
		PC 20D			В		3										
		PC 19D				3		A									
		PC 18D			٥	0				0							
		C 17D			В												
		C 16D										В					
		PC 15D															
		PC 14D															
		PC 13D			Э							В					
		PC 12D					O										
llenge		C 11D										٥					
st Cha		10DF															
erved Po		OMO6														served	
Signs Obse	SC Vaccinates	8DPC				u.	E						ine	3.0°F		Blank - no clinical Sign observed	
ero Clinical	SC	7DPC											K - Bloody Urine	L - Fever >103.0°F	M - Death	Blank - no cl	
Leptospira Ictero Clinical Signs Observed Post Challenge		0PC	A			ш					В	0				stool)	ol)
l a		SDPC			0							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				SI	pio
		2DPC										0			C - Depression/Lethargy	D- Ocular Discharge Serous	E - Ocular Discharge Mucoid
		1DPC					A,E						etance	ing	ession/	r Disch	ır Disch
		0DPC											A-inappetance	B-Vomiting	C - Depr	D-Ocula	E-Ocula
		Dog	11	12	13	14	15	16	17	18	19	20					

DPC = Day post-challenge

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		21DPC																	
		20DPC																	
		19DPC		ш	ш														
		18DPC			ш						O		O	8					
		17DPC			ш														
		16DPC			ш								П						
		15DPC							0										
		14DPC																	
		13DPC																	
		12DPC			ш				Б										
age e		11DPC								M		M	E						
Challe		100PC 110PC 120PC 130PC 140PC 150PC 170PC 180PC 190PC 200PC 210PC								~		V							
Post (9DPC																_	
erved		36																bservec	
Leptospira Ictero Clinical Signs Observed Post Challenge	slo.	8DPC							A									Blank - no clinical Sign observed	
al Sign	Controls														/Urine	103.0°F	_	clinica	
Ginic		7DPC							_						K - Bloody Urine	L - Fever >103.0°F	M - Death	ank - no	
ctero															ż	ن	Σ	<u>=</u>	
ospira		6DPC	A										A	ш				=	
Lept																ъ	(100	eny sto	(stool)
		SDPC							Б		0				Serous	e Mucoi	oose st	te (Wat	(plood)
															scharge	ischarg	Mild (Modera	Severe
		4DPC	ı.	ᇤ					٥	A,C,D,J		A,E			F - Nasal Discharge Serous	G - Nasal Discharge Mucoid	H- Diarrhea Mild (loose stool)	I- Diarrhea Moderate (Watery stool)	J - Diarrhea Severe (bloody stool)
															Œ	-6	꿒	-	=
		3DPC			_	1			Q	Х		ΓΊ	3					S	ë
		2DPC			_	_			_	L,E	_		_				thargy	ge Sero	rge Muc
		1DPC												П	ance	50	ssion/Le	Dischar	Discha
		ODPC :													A-inappetance	B-Vomiting	C - Depression/Lethargy	D- Ocular Discharge Serous	E - Ocular Discharge Mucoid
						_		,-			_				-H	&	ن	۵	ய்
		Dog	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	7.5	7.8	8.8	8.1
		12DPC	9.6	6	7.8	10	11.1	10	10.2	6.5	7	7.6
		11DPC	6.7	10.2	6.7	8.6	7.7	9.5	7.1	8.1	7.8	12.6
		10DPC	8.9	7.7	10.6	13.2	10.4	8.7	11.7	6	7.7	12.5
Challenge		9DPC	8.5	9.8	8.3	8	7.5	7.7	7.6	8	8.2	8.7
Leptospira ictero White Blood Cell Count Post Challenge		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	90РС	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
		3DPC	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	7.6	11.4	8.8	7.1	7.7	13.8.	6.6
		Baseline (Avg -2DPC, -1DPC, 0DPC)	7.2	10	7.6	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 Bloc	od Cell Co	unt Post	Leptospira ictero White Blood Cell Count Post Challenge					
							Cont	Controls							
Dog	Baseline (Avg -2DPC, -1DPC, 0DPC)	1DPC	2DPC	3DPC	4DPC	SDPC	брРС	7DPC	8DPC	9DРС	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	6.3	8.2	5'9	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	1.7	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	6	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	8.6	7.5	8.6	12.1	9.8	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]	D				
30	8.8	7.6	5	7.2	7.8	7.5	7.8	6.2	6.6	8	10.3	10.1	6.6	9.4	9.6
31	11	8.1	8.3	4.2	19]	D				
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
eptospira ictero Platelet Counts Post Challenge		8DPC	488	480	416	376	314	281	513	327	378	392
Counts	nates	7DPC	447	435	517	335	400	268	457	419	500	352
Platelet	SC Vaccinates	6DPC	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
Lep		3DPC	476	447	560	349	286	217	386	392	552	483
		2DPC	619	456	425	413	297	298	400	569	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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			_							_					
		14DPC	410	367	535	451	409	388	474	383		427		301	
		13DPC	414	386	583	658	432	452	372	467		421		287	
		12DPC	399	369	422	461	427	513	540	495		411		337	
		11DPC	434	421	444	635	519	578	461	618		494		360	
		10DPC	575	520	546	618	660	467	469	622		642		529	
allenge		9DPC	537	412	447	480	466	444	575	612	D	516	D	430	
Post Ch		8DPC	529	340	369	440	458	421	465	467		549		525	
Counts	slo	7DPC	206	288	361	497	611	381	437	332		512		347	
Platelet	Controls	6DPC	545	261	393	312	483	361	386	307		379		257	
ictero		5DPC	341	184	362	189	288	210	335	213		231		196	
Leptospira ictero Platelet Counts Post Challenge		4DPC	301	126	289	116	189	84.5	413	128	11.2	119	11.9	88.8	
Lep		3DPC	207	168	265	99.5	146	94.9	483	60.5	6.7	53.9	36.7	7.7	
		2DPC	315	250	307	130	220	213	423	93.5	101	80.9	94.4	55	
		1DPC	291	238	374	251	401	302	399	214	136	204	163	184	
		Baseline (Avg -2DPC, -1DPC, 0DPC)	534.3	428.7	411.3	344.7	266	392	475.7	411.7	332	421.9	319.3	267	9
		Dog	21	22	23	24	25	26	27	28	29	30	31	32	D = Dead

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.
USDA Approval Date	January 12, 1999
OSDA Appiovai Date	various 12, 1777

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Isolation of Leptospira from Blood Collected from Dogs Post Challenge

							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	Cannie Distemp	er Virus (CDV))										
Study Purpose	To demonstrate	effectiveness a	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 obser	rved for 42 day	s after challenge fo	or clinical signs									
challenge	of CDV.												
Results	The study was so (b)(3) (i-ii)	atisfactory per	the criteria in 9 CF	R 113.306									
	(b)(3) (i-ii) 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 a	ppended to the	end of this summa	ıry									
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							
	00PC 10PC 20PC 40PC 50PC 60PC 70PC 80PC 100PC 110PC 120PC 130PC 140PC 150PC 160PC 180PC 190PC 200PC 210PC									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	were not considered clinical signs of CDV				
ogs	16DPC												nor sto	dered				
ted D	15DPC												ttent m	ot consi	ć.			
ccina	14DPC											П	Intermit	were no	infection.			
- Va	13DPC												Ī					
llengo	12DPC	Г										П						
CDV Clinical Signs Observed Post Challenge - Vaccinated Dogs	11DPC	Г																Blank - No Clinical signs observed
od Po	10DPC	Г												ation	its	rTics		signs
Observ	9DPC												50	16 - Excessive Salivation	17 - Chewing gum fits	18 - neuromuscular Tics		Clinical
Signs	SDPC											Ц	14 - Vomiting	Excessi	Chewin	neurom	20 - death	ik - No
s leal	C 7DP	L						27.5		_		Н	14 -	16 -	17 - (18-	20-	Blan
V Clir	PC 6DF	Н										Н		picon				
8	DPC SD	Н		L			10					Н		M egs				
	DPC 40	Н		-			-			Н		Н	Vare	Discha				
	DPC 30	H	H	-						H		Н	n/Leth	Ocular	c	100	-	5
	DPC 2	H										\parallel	ression	/Mod.	ydratio	ous st	ery Sto	dy sto
	0DPC 1												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						

DPC – Days post-challenge

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					ŭ	CDV Clini	cal Sig	ns Obs	erved	Post	Clinical Signs Observed Post Challenge - Vaccinated Dogs	nge -	Vacci	nated	Dog	S					
									S	SC Vaccinates	notes										
Dog	22DPC	23DPC	24DPC	25DPC	22DPC 23DPC 24DPC 25DPC 26DPC	27	28DPC	DPC 28DPC 29DPC 30DPC 31DPC 32DPC 33DPC 35DPC 35DPC 37DPC 38DPC 39DPC 41DPC 42DPC	30DPC	31DPC	32DPC	33DPC	34DPC	35DPC	36DPC	37DPC	38DPC	39DPC 4	40DPC 4	11DPC 4	42DPC
	11									Г								l			
				10,12													14				
	10				10	10	10		12												
				27.5																	
						10		10	10												
	11,12	П	10,12		10,12	10,11,12	12														
	11	10,12	10,12					10,12				12	12	12		12			12		
	1 - Depression/Lethargy	ession	/Lethar	Ass				14 - Vomiting	niting					Ī	ntermit	tent mi	nor stor	ol abno	Intermittent minor stool abnormalities observed	s obser	rved
	2- Mild/	Mod. 0	cular D	ischarg	2- Mild/Mod. Ocular Discharge Mucoid	p		16 - Exce	essive S	16 - Excessive Salivation	u				were no	tconsid	dered cl	inical s	were not considered clinical signs of CDV	CDV	
	8 - Dehydration	dration	_					17 - Chewing gum fits	wing gu	um fits					infection.	ď					
	10-Mucous stoo	ous sto						18 - neu	romusc	18 - neuromuscular Tics	n										
	11-watery Stool	ny Stoo						20 - death	th												
	12-Bloody stool	dy stoo	_					Blank - No Clinical signs observed	No Clini	ical sign	ns obse	pavi									

 $DPC-Days\ post-challenge$

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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												
	9DPC							9DРС										D							
trols	SDPC		С					SDPC																	
ated Con	7DPC		С	-	-		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	Н,			SDPC											O						
	4DPC			I				4DPC																	
	3DPC							3DPC																	
	2DPC							2DPC													Q				
	1DPC	۵						1DPC											Q						
	0DPC							0DPC			D														
	Dog	1	2	က	4			Dog	1	2	8	4	2	9	7	80	6	10	11	12	13	14	15	16	17

DPC = Days Post Challenge

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

H - Vomiting I - Death

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Daily Rectal Temperature (°F)

		_	_	_	_	_		_	_		_	_	_	_		_	_		
	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	
	8DPC	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	1001	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	1.101	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	affenge
	0DPC	101.1	101.1	101.0	100.7	101.0	101.3	100.5	99.7	100.5	101.3	101.3	100.9	6.66	69.7	100.7	100.9	101.8	rs Post CL
	Cat ID	2	9	7	00	6	10	11	12	13	14	15	16	17	18	19	20	21	DPC = Davs 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	0.6	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	SDPC	13.9	12.7	15.6	6.3
n-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

	5																	
	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	9.8	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	9.7	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	8.6	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	2	9	7	80	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
CPV Titer From Fecal Material (Log FAID ₅₀ /mg Feces)	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
r From Fe	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	41.5
	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	<1.5
	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	41.5
Vaccinates	SDPC	NS	41.5	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	<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
	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
	1DPC	<1.5	41.5	<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	<1.5
	Cat ID	5	9	7	80	6	10	11	12	13	14	15	16	17	18	19	20	21

<1.5 is considered negativeNS = No sampleDPC = 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

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1,2,3 1,2,3 1,2,3 2,3,4	Dog ID (0DPC	1DPC	2DPC	3DPC	4DPC	C SDPC		₽	8DPC	9DPC	15	10DPC	DPC 11DPC	\blacksquare	11DPC
1,2,3 1,2,3 1,2,3 2,3	9						1,2,3	\dashv	1,2,3	\dashv	Na		Na	Na Na		Na
1 1 1 1 2,3 1,3	1						1,2,3	Н	1,2,3	Н						
2,3 1,3 1,3	19							1	1	1		-				
Vaccinates	21			T	T	\dagger	+		2,3	1,3						
### Table Ta	į						-		\mid	f					-	
ODPC IDPC 2DPC 3DPC 4DPC 5DPC 5DPC 8DPC 1								_	/accinates							
	Dog ID (0DPC	1DPC	-	-	-	${}$	т	Н	${}$	9DPC	ದ	PC 10DPC	\Box	10DPC	10DPC 11DPC
	1															1,3
	2										П					
	S												1	1	1	1
	4	1														
	5															
	6															
1	7															
	8	Ľ														
	10											- 1				
	13											_ I				
12	14															
	15															1
1-1	16															
	17									1	2					
	18											l i				
	20															
	22															
24 28 28 28 28 28 28 28 28 28 28 28 28 28	23	1														
28	24															
	28															
	000	Stool			3-B1000g/51001	out a con	1	Blank	. No climic	Blank - No clinical signs observed	PSPILIPS	_	_	_	_	

DPC – Days Post Challenge

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24	24	!	23	22	20	18	17	16	15	14	13	10	8	7	6	5	4	3	2	_	Dog ID		17	27	19	1	9	Dog ID		
128	120	4	2	<2	45	16	32	8	23	32	181	128	512	1448	1024	2048	153	54	64	91	-24DPV1		5	\$ 6	23	91	724	-24DPV1		
32	3	1	8	11	11	23	32	11	6	8	6	45	32	6	23	45	64	45	32	32	0DPV1		c	2	64	4	8	0DPV1		
6	10	4	11	8	4	19	23	11	2	16	6	64	8	4	23	16	23	23	23	8	7PV1		٥	70	23	ω	4	7PV1		
2>	اد	2	<2	<2	<2	<2	5	2	<2	2	<2	2	<2	<2	<2	<2	<2	2	<2	<2	28DPV1 (0DPV2)	Vaccinates	7	۵۵	2	<2	<2	28DPV1 (0DPV2)	Non-Vaccinated Controls	Serum Neutrlization Titer
1448	1110	1024	1448	4	724	512	<2	<2	512	<2	45	<2	<2	1024	<2	45	724	1024	362	1024	41DPV1	ates	4	\$ 6	2	-2	<2	41DPV1	ed Controls	zation Titer
4096	Anne	16384	NO TEST	8192	8192	23170	11585	9767	11585	2896	2048	11585	2896	8192	512	4096	19534	5793	6871	11585	56DPV1		4	2 (2	2	<2	<2	56DPV1		
11585	11505	23170	16384	11585	16384	11585	8192	11585	11585	4884	5793	11585	11585	8192	2896	8192	23170	5793	16384	11585	70DPV1		4	\$ 6	2	2	<2	70DPV1		
1976	0767	16384	11585	8192	11585	11585	16384	23170	16384	11585	8192	11585	=>46341	=>23170	9767	23170	=>46341	6871	16384	=>23170	84DPV1 (0DPC)		7	۵ ۵	2	<2	<2	84DPV1 (0DPC)		

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28	24	23	22	20	18	17	16	15	14	13	10	8	7	6	5	4	ω	2	1	CatID		27	21	19	11	9	CatID	
2.43	0.97	0.84	3.80	1.83	2.06	2.25	1.68	2.21	2.17	1.26	2.74	2.07	1.23	1.43	0.62	1.10	2.09	2.45	3.05	-2DPC		2.68	1.67	1.57	2.24	1.24	-2DPC	
2.68	2.04	1.46	3.05	2.11	2.82	2.14	2.54	2.30	2.24	2.25	2.80	1.89	1.22	1.84	0.96	1.59	2.40	2.50	3.06	-1DPC		2.26	2.19	2.14	2.59	1.20	-1DPC	
2.15	2.32	1.51	3.35	2.05	2.50	2.11	2.06	2.66	3.02	2.24	3.27	2.00	1.18	1.73	1.16	2.46	2.34	2.34	2.74	0DPC		2.30	2.52	1.87	2.07	1.38	0DPC	
2.42	1.78	1.27	3.40	2.00	2.46	2.17	2.09	2.39	2.48	1.92	2.94	1.99	1.21	1.67	0.91	1.72	2.28	2.43	2.95	Average		2.41	2.13	1.86	2.30	1.27	Average	
2.68	2.09	1.63	3.96	2.58	2.97	2.42	2.56	3.10	3.57	2.43	1.93	1.81	1.18	1.84	1.23	3.23	2.42	3.32	2.05	1DPC		2.29	2.68	2.32	2.28	1.71	1DPC	Controls
2.89	2.24	1.35	3.18	2.22	2.48	2.84	2.08	2.81	3.62	1.88	2.43	1.93	1.51	1.55	1.32	2.45	2.46	3.05	2.25	2DPC	Va	2.37	1.92	2.26	2.36	1.45	2DPC	C
3.56	2.67	1.47	3.38	2.39	2.62	2.62	3.35	3.04	3.76	2.57	2.56	1.78	1.53	1.16	1.14	2.91	2.32	3.27	2.42	3DPC	Vaccinates	2.25	2.31	2.42	1.82	0.80	3DPC	Controls
3.56	2.03	1.45	3.75	2.50	3.05	2.93	2.83	2.85	3.28	2.39	3.01	1.52	1.68	1.79	1.26	2.03	1.65	3.03	2.39	4DPC		0.92	1.17	1.42	0.29	0.30	4DPC	
2.52	2.03	1.29	2.36	1.73	3.04	2.69	2.35	2.98	3.07	2.57	2.65	1.64	1.52	1.62	1.19	2.75	1.73	2.73	2.66	5DPC		1.00	0.67	0.70	0.58	0.28	5DPC	
2.46	2.70	1.72	2.42	1.98	3.98	3.04	3.13	3.29	3.66	3.09	2.44	2.52	1.81	2.44	1.57	2.34	2.38	3.20	3.31	6DPC		1.09	1.75	1.59	0.69	0.74	6DPC	
3.57	2.46	1.53	3.93	2.12	3.27	2.78	2.90	2.51	4.10	3.22	2.65	2.23	0.22	1.97	1.49	2.41	2.16	3.23	2.57	7DPC		2.04	2.03	1.66	1.04	0.27	7DPC	
3.61	2.68	1.44	3.23	2.28	2.26	1.34	2.27	0.93	4.18	3.24	2.64	2.51	1.67	2.32	1.36	2.87	2.42	2.92	3.01	8DPC		1.74	1.52	1.52	1.17	Na	8DPC	
3.50	2.86	1.14	3.34	2.35	3.98	2.59	3.24	2.71	4.57	3.17	2.83	2.59	1.91	2.24	1.09	2.66	2.52	3.28	2.64	9DPC		2.08	2.09	2.11	1.27	Na	9DPC	
0.92	3.54	1.22	4.33	3.26	4.78	3.28	3.30	2.59	4.83	2.72	2.76	2.38	2.33	2.77	1.98	3.12	2.10	1.67	3.14	10DPC		2.60	3.35	2.70	2.13	Na	10DPC	

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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	Na
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	9DPC
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	103
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
30	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	<u> </u>	CatID		27	21	19	1	9	CatID	
CPV >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	≤1.5	0DPC		s1.5	s1.5	≤1.5	≤1.5	≤1.5	0DPC	
>1.5 log10 FAID50/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		<u>~1.5</u>	s1.5	≤1.5	≤1.8	≤1.5	1DPC	
I me/	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	≤1.5	2DPC		<u><1.5</u>	×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		<u><1.5</u>	<u><18</u>	≤1.5	≤1.5	≤1.5	3DPC	
	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	≤1.5	4DPC	Vacc	≤2.8	4.3	2.5	5.5	≤2.5	4DPC	Col
	≤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	≤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	7DPC		6.6	6.8	7.6	≥8.5	5.2	7DPC	
	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	≤1.5	8DPC		52	≤2.8	4.2	≥8.6	≥9.2	8DPC	
	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	s1.5	9DPC		≤3.0	4.5	4	≥7.6	Na	9DPC	
	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	≤1.5	10DPC		<u><1.5</u>	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	* *	
Product Administration	Two doses were administered subcu	taneously appi	oximately two
	weeks apart.		
Study Animals	A total of 675 dogs, privately owned		
	were enrolled in the study. From the	•	
	age or younger, at first vaccination.	I nree geograp	nical sites were
Challes a Denselation	represented.		
Challenge Description Interval observed after	NA Animals were observed 30 minutes	often anala vana	ination and daily
			ination and dairy
challenge Results	for two (2) weeks after each vaccinate Frequency of adverse events:		
Results	rrequency of adverse events.		
		Number of Animals	Percent of Animals
	No observed adverse events	628	
			93.0%
	Injection Site Lesion	1	0.1%
	Diarrhea-one day of loose stools	23	3.4%
	Heavy Breathing	1	0.1%
	Death-Hit by Car *	1	0.1%
	Death-depression, decreased	1	0.10/
	appetite, weight loss **	1	0.1%
	Lameness (leg cramp) *	1	0.1%
	Decreased appetite, weight loss, diarrhea, and dehydration *	4	0.6%
	Gastroenteritis (vomiting) *	2	0.3%
	Laceration *	1	0.1%
	Prolapsed nictitan gland *	7	1.0%
	Pyoderma *	5	0.7%
	J • • • • • • • • • • • • • • • • • • •		
	*Affirmed by study investigator to h	nave cause othe	er than
	vaccination		
	**Cause of death was not determine	•	0
	appeared 4 days after vaccination ar	nd death 8 days	later.
		1.6	, ,
	The injection site lesion was detected	atter the seco	ond vaccination
	and resolved within 15 days.		
LICDA Approved Dete	13 Jan 2011		
USDA Approval Date	13 Jan 2011		

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