

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	4637.29
True Name	Canine Distemper-Adenovirus Type 2-Parainfluenza- Parvovirus Vaccine, Modified Live Virus, Leptospira Canicola- Grippotyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Duramune Max 5/4L - 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	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			pies, seronegative	
	randomly sorted	into one group	of 11 SC vaccinat	es and one
	group of 6 contr			
Challenge Description	21 days after sec	cond vaccinatio	n all dogs were cha	allenged with
	Infectious Canir	ne Hepatitis Vir	us.	
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%)	
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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						ocular discharge		6							6		
	1 - Depression	on/Let	nargy			6 - Serous o			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
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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															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		П		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	platio	n fron	n Nas	al Swa	ab Sar	nples	TCID	CAV2 Isolation from Nasal Swab Samples (TCID ₅₀ /100uL)	nr)						
Dog	Group	ODPC	1DPC	2DPC	3DPC	4DPC	SDPC	6DPC	7DPC	8DPC 9	9DPC 1	100PC 1	1DPC 1	2DPC 1	3DPC 14	100PC 110PC 120PC 130PC 140PC 150PC 160PC	DPC 160		C 18DPC	17DPC 18DPC 19DPC 20DPC	20DPC	21DPC
1	Control				2	2.5	3.63	3.5	51.83		Г			Н	H	H	H	L	L		Г	
2	Control				2	2.83	3.5	3.83	2.17							51	51.83					
က	Control				\$1.63	3.5	4.17	3.38							.,	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				\$1.83	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				\$1.63	2.83	2.83	4.38												51.83		
10	Control				\$1.63	2.17	3.63	3.5					51.63	2.38	2.5 ≤	51.83						
11	Control				≤1.83	2.5	4.5	4.38					*1	51.63	51.83	51.63 51	51.63	51.63	60	51.63		
23	SC																					
24	SC		51.6				2.38															
25	SC					51.63																
56	SC								2.63													\$1.63
27	SC		≤1.63											*"	51.63							
28	SC										-	51.63										
53	SC				2	≤1.83								*1	≤1.63	12	<1.63					
30	SC																					
31	SC													*1	≤1.63							
32	SC		51.6			≤1.83	2.63	2.5														
33	SC															51	s1.63					
Blank	Blank - No CAV2 titer detected	titer de	rected	_																		
DPC-	DPC - Days Post Challenge	Challer	98																			

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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 <i>L. canicola</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 1
	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 loukenenic if the platelet count
	A dog was considered to have leukopenia if the platelet count dropped below $6 \text{ k/}\mu\text{L}$ and the count was less than 50% of the
	baseline value.
	baseinie value.
	Data tables are appended to the end of this summary.
	Data tables are appended to the one of this summary.
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		21DPC																		
		20DPC		9	8															
		19DPC			8									o	Ī					
		10DPC 11DPC 12DPC 13DPC 14DPC 15DPC 16DPC 17DPC 18DPC 19DPC 21DPC				9								DPC = Day post-challenge	0					
		17DPC							AG					st-cha						
		16DPC				g							Ŧ	av po						
		15DPC			A	AG			A					Q = D						
		14DPC							A					DP(
		13DPC																		
		12DPC																		
enge		11DPC																		
t Chal		10DPC				A														
erved Pos		9DPC									9								perved	
Signs Obs	SC Vaccinates	8DPC												3.0-103.9°F)	1.0-104.9°F)	5.0-105.9°F)			nical signs of	
ola Clinical	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	
Leptospira canicola Clinical Signs Observed Post Challenge		6DPC				9						А								
Lept		SDPC									9	9		G - Ocular Discharge Mucoid	harge Serous	I - Nasal Discharge Mucoid	J - Diarrhea Mild (loose stool)	K - Diarrhea Severe (bloody stool)	e e	
		4DPC						9	A		9			G - Ocular Dis	H - Nasal Discharge Serous	I - Nasal Disch	J - Diarrhea M		L - Bloody Urine	M - Icterus
		3DPC						9				9						derate		
		2DPC					9				9	AD				guin	ethargy	E1 - Conjunctivitis Mild/Moderate	E2 - Conjunctivitis Severe	F- Ocular Discharge Serous
		1DPC		A	A	0	O					A		tance	20	d Breat	Ssion/l	unctiviti	unctiviti	Discha
		0DPC				9			9		9	9		A-inappetance	B-Vomiting	C-Labored Breathing	D - Depression/Lethargy	E1 - Conj	E2 - Conju	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 9.5 9.3 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	260	302	261	480	414	601	521	200
		10DPC	512	501	267	482	519	270	405	381	493	501	492
llenge		90РС	631	470	695	497	512	288	483	476	662	581	297
s Post Cha		8DPC	478	292	693	576	655	314	463	379	704	650	473
let Count	SC Vaccinates	7DPC	582	989	604	633	558	351	247	375	706	514	469
ola Plate	SC Vac	бРРС	531	467	497	612	555	389	542	376	538	441	517
Leptospira canicola Platelet Counts Post Challenge		SDPC	512	539	536	503	492	329	453	375	523	469	576
Leptos		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	655	452	381	409	247	356	353	497	354	455
		1DPC	538	629	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
		Bog	12	13	14	15	16	17	18	19	20	21	22

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 $k/\mu L$.

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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.
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	O				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	E														
		18DPC			Е						0		0	8					
		17DPC			Б														
		16DPC			Е								Е						
		15DPC							٥										
		14DPC																	
		13DPC																	
		12DPC			Б				ш										
nge		11DPC								W		M	Б						
Challe		100PC 110PC 120PC 130PC 150PC 160PC 170PC 180PC 190PC 200PC 210PC										\ \							
Post		9DPC																_	
served		16																bserve(
Leptospira Ictero Clinical Signs Observed Post Challenge	slo	8DPC							A									Blank - no clinical Sign observed	
al Sig	Controls														/ Urine	L - Fever >103.0°F	_	clinica	
Clinic		7DPC							_						K - Bloody Urine	· Fever	M - Death	ank - no	
cter															~	_	2		
ospira		6DPC	A										A	ш				=	
Lept																ъ	(100	eny sto	(stool)
		SDPC							ш		٥				Serous	e Mucoi	oose st	te (Wat	(blood
															scharge	ischarg	Mild (Modera	Severe
		4DPC	u.	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)
															£	-6	Ξ	<u>-</u>	=
		3DPC			_	_			٥	~		L,D	ш					Sn	ë
		2DPC			_	_			_	L,E	_		_				thargy	ge Sero	ge Muc
		1DPC												H	auce	be	sion/Le	Dischar	Dischar
		0DPC 1													A-inappetance	B-Vomiting	C - Depression/Lethargy	D- Ocular Discharge Serous	E - Ocular Discharge Mucoid
														H	Ą-	4	ن	۵	ய்
		Dog	21	22	23	24	25	26	77	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	9	7.8	10	11.1	10	10.2	6.5	7	7.6
		11DPC	6.7	10.2	6.7	9.8	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	9	7.7	12.5
Challenge		9DPC	8.5	9.8	8.3	8	7.5	7.7	9.7	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	зррс	4DPC	SDPC	6DPC	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	9.3	8.2	6.5	7.3	13.4	9.4	7.2	8.2	13.4	10.1	1.7	7.6	9.4
23	9.3	12.2	9.4	11.6	7.1	6	10	7	6.5	7.1	11.9	4	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	8.6	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]	D				
30	8.8	7.6	5	7.2	7.8	7.5	7.8	6.2	6.6	80	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	6.6	10	10.1	9.3
D = dead															

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

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	_											
		14DPC	359	212	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
hallenge		OdQ6	442	205	208	331	285	253	436	424	489	358
eptospira ictero Platelet Counts Post Challenge		SDPC	488	480	416	376	314	281	513	327	378	392
Counts	nates	7DPC	447	435	517	335	400	268	457	419	200	352
Platelet	SC Vaccinates	90РС	457	645	445	344	435	308	542	393	459	555
ictero		SDPC	299	526	580	374	282	278	214	351	417	515
ptospira		4DPC	440	428	424	457	275	264	332	397	529	525
Le		3DPC	476	447	260	349	286	217	386	392	552	483
		2DPC	619	456	425	413	297	298	400	995	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	506	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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				Leg	otospira	ictero	Platelet	Leptospira ictero Platelet Counts Post Challenge	Post C	nallenge	•				
							Controls	slo							
Dog	Baseline (Avg -2DPC, -1DPC, 0DPC)	1DPC	2DPC	зррс	4DPC	5DPC	9 ервс	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						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						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.
USDA Approval Date	January 12, 1999
Cobii rippi orai bate	

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Isolation of Leptospira from Blood Collected from Dogs Post Challenge

							Cont	rol Anir	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

Pertaining toCanine Parainfluenza VirusStudy PurposeTo demonstrate effectiveness against Canine Parainfluenza Virus (CPI)Product AdministrationTwo doses were administered by the subcutaneous (SC) route three (3) weeks apartStudy AnimalsNineteen (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 Description21 days after second vaccination all dogs were challenged with CPIInterval observed after challengePuppies were observed for 21 days after challenge for clinical signs. Blood and nasal swabs were collected during this period.ResultsThe 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:Raw Data:	Study Type	Efficacy
Product Administration Two doses were administered by the subcutaneous (SC) route three (3) weeks apart 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 Challenge Description Interval observed after challenge Puppies were observed for 21 days after challenge for clinical signs. Blood and nasal swabs were collected during this period. 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:	Pertaining to	Canine Parainfluenza Virus
Product Administration Two doses were administered by the subcutaneous (SC) route three (3) weeks apart Study Animals Nineteen (19) 6 week old puppies seronegative for CPI were randomly sorted into one group of 13 SC vaccinates and one group of 6 controls. Challenge Description 21 days after second vaccination all dogs were challenged with CPI Interval observed after challenge Puppies were observed for 21 days after challenge for clinical signs. Blood and nasal swabs were collected during this period. Results 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: Raw Data:	Study Purpose	To demonstrate effectiveness against Canine Parainfluenza Virus
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 Interval observed after challenge Puppies were observed for 21 days after challenge for clinical signs. Blood and nasal swabs were collected during this period. Results 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:		(CPI)
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	Product Administration	Two doses were administered by the subcutaneous (SC) route
randomly sorted into one group of 13 SC vaccinates and one group of 6 controls. Challenge Description 21 days after second vaccination all dogs were challenged with CPI Interval observed after challenge Puppies were observed for 21 days after challenge for clinical signs. Blood and nasal swabs were collected during this period. 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:		three (3) weeks apart
Challenge Description Interval observed after challenge Puppies were observed for 21 days after challenge for clinical signs. Blood and nasal swabs were collected during this period. Results 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:	Study Animals	1 11
Challenge Description 21 days after second vaccination all dogs were challenged with CPI Interval observed after challenge Puppies were observed for 21 days after challenge for clinical signs. Blood and nasal swabs were collected during this period. 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:		randomly sorted into one group of 13 SC vaccinates and one
Interval observed after challenge CPI Puppies were observed for 21 days after challenge for clinical signs. Blood and nasal swabs were collected during this period. 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:		<u> </u>
Interval observed after challenge Puppies were observed for 21 days after challenge for clinical signs. Blood and nasal swabs were collected during this period. 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:	Challenge Description	
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:		
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:		, 11
response in vaccinates and the decrease in the number of days of virus shedding in vaccinates when compared to controls. Raw Data:		<u> </u>
virus shedding in vaccinates when compared to controls. Raw Data:	Results	
Raw Data:		
		virus shedding in vaccinates when compared to controls.
		Pays Dates
Data tables are appended to the and of this symmetry		
Data tables are appended to the end of this summary		Data tables are appended to the end of this summary
USDA Approval Date March 16, 1998	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 0	20014									
208 0	DDPV1	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

					•		Joiati								
							Co	ontrol	S						
Do g	ODP C	1DP C	2DP C	3DP C	4DP C	5DP C	6DP C	7DP C	8DP C	9DP C	10DP C	11DP C	12DP C	13DP C	14DP C
1	-	+	+	+	+	+	+	-	-	-	-	-	-	-	-
2	-	+	+	+	+	+	+	-	-	-	-	-	-	-	-
3	1	+	+	+	+	+	+	-	+	-	-	-	-	-	1
4	-	+	+	+	+	+	+	-	+	-	-	-	-	-	-
5	-	+	+	+	+	+	+	+	-	-	-	-	-	-	-
6	-	+	+	+	+	+	+	+	+	-	-	-	-	-	-
							SC V	accina	ates						
Do g	ODP C	1DP C	2DP C	3DP C	4DP C	5DP C	6DP C	7DP C	8DP C	9DP C	10DP C	11DP C	12DP C	13DP C	14DP C
20	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
21	-	+	+	+	+	+	=	-	-	-	-	-	-	-	-
22	-	+	+	+	+	+	-		+	-	-	-	-	-	-
23	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
24	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
25	-	+	+	+	+	+	-	-	+	-	-	-	-	-	-
26	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
27	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
28	-	+	+	+	+	+	+	-	+	-	-	-	-	-	-
29	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
30	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
31	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
32	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-

[–] 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 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
		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 were not	101101101				
o	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	premittent minor stool shoormalities observed were not	out ability infaction	gils of cov fillection.			
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 st	menimicent minor stool appromises of	considered cillical s			
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	scular Tics		Blank - No Clinical signs observed
ical 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 Clin	3DPC	10,12,18	2,10,12	2,10,12	2,10,12			14DPC	20	20	1,8,9,10,12	20		20		id				
	2DPC	10,12,18						13DPC	20	20	8,10,11	20	2,11	20	,	2- Mild/Mod. Ocular Discharge Mucoid				
	1DPC							12DPC	20	20	1,8,10	20		1,2,8,12	1 - Depression/Lethargy	d. Ocular Di	tion	stool	tool	tool
	ODPC							11DPC	20	20	8,10,12	20	8,10,12,14	1,2,8,10,12	1 - Depress	2- Mild/Mo	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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					9	Clinic	al Sig	O su	Serv	ed Po	st Ch	alleng	- V	accina	Clinical Signs Observed Post Challenge - Vaccinated Dogs	Sogs					
										SC Vo	SC Vaccinates	es									
Dog	0DPC 1	0DPC 1DPC 2DPC 3DPC 4DPC 5DPC	C 3DP	C 4DPC	SDPC	6DPC	7DPC	8DPC 5	DPC 1	ODPC	11DPC	12DPC	13DPC	14DPC	15DPC	16DPC	17DPC	18DPC	19DPC	6DPC 7DPC 8DPC 9DPC 10DPC 11DPC 12DPC 13DPC 14DPC 15DPC 16DPC 17DPC 18DPC 19DPC 21DPC	21DPC
18		H	L	L				П	Н												10,12
19																	14				
20																			10		
21																					
22																					
23				10																	
24						77.															
25																					
26						, X														12	
27																	10,12	11,12	11,12	12	12
28																	10,12		10,12		
	1 - Depr	1 - Depression/Lethargy	Letharg	2			14 - Vo	14 - Vomiting						Interm	ittent n	ninor st	Intermittent minor stool abnormalities observed	ormalit	ties obs	perved	
	2- Mild,	2- Mild/Mod. Ocular Discharge Mucoid	ular Di	scharge	e Mucc	pic	16 - Ex	16 - Excessive Salivation	Salive	ation				were	ot cons	idered	were not considered clinical signs of CDV	signs o	of CDV		
	8 - Deh	8 - Dehydration					17 - Ch	17 - Chewing gum fits	gum fi	ts				infection.	on.						
	10-Muc	10-Mucous stoo	_				18 - ne	18 - neuromuscular Tics	scular	Tics											
	11-wate	11-watery Stool					20 - death	ath													
	12-8100	12-Bloody stool					Blank	- No CI	nical	Blank - No Clinical signs observed	bserve	g									

DPC – Days post-challenge

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					O	CDV Clini	Clinical Signs Observed Post Challenge - Vaccinated Dogs	us Co	Servec	L LOSE	Challe	- agus	Vacc	uate	J DOE	20					
									-1	SC Vaccinates	notes										
Dog 2	2DPC	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	40DPC 4	11DPC 4	42DPC
-	11																				
-																					
				10,12													14				
	10				10	10	10		12												
-																					
Н	Ħ					10		10	10												
	11,12		10,12		10,12	10,11,12	12														
	11	10,12	10,12					10,12				12	12	12		12			12		
	- Depr	ession	1 - Depression/Lethargy	A.S				14 - Vomiting	niting						Intermit	tent mi	nor sto	ol abno	Intermittent minor stool abnormalities observed	s obser	pen
17	/pilly	Mod. 0	Cular D	Discharg	2- Mild/Mod. Ocular Discharge Mucoid	pi		16 - Exc	essive S	16 - Excessive Salivation	uc			ĺ	were no	tconsid	dered cl	linical s	were not considered clinical signs of CDV	CDV	
00	- Dehy	8 - Dehydration						17 - Che	17 - Chewing gum fits	um fits					infection.	٠.					
-	0-Muco	10-Mucous stoo	lo					18 - net	romuse	18 - neuromuscular Tics	27										
-4	1-wate	11-watery Stool	_					20 - death	oth												
-	2-Blood	12-Bloody stool	_					Blank -	No Clin	Blank - No Clinical signs observed	ns obse	pava									

 $DPC-Days\ post-challenge$

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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	Puppies were observed daily for 14 days after challenge
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		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	G,H		SDPC											٥						
	4DPC			I			4DPC																	
	3DPC						3DPC																	
	2DPC						2DPC													D				
	1DPC	۵					1DPC											D						
	0DPC						0DPC			D														
	D B D	1	2	က	4		Dog	1	2	3	4	2	9	7	80	6	10	11	12	13	14	15	16	17

H - Vomiting I - Death E - Watery Stool F - Bloody Stool G - Anorexia B - Lethargy C. Dehydration D - Mucous Stool

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
Controls	SDPC	101.3	101.0	Na	Na
inated (7DPC	101.3	101.0	eN	Na
Non-Vaccinated Controls	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	2.66	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	
	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	eN	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

	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	5DPC	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	2	9	7	8	6	10	11	12	13	14	15	16	17	18	19	20	21

DPC = Days Post Challenge

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		10DPC	1.5	3.4	NS	NS
		9DPC	2.0	3.5	NS	NS
		8DPC	5.2	4.5	NS	NS
ng Feces		7DPC	5.5	5.4	NS	NS
FAID ₅₀ /1	trols	6DPC	5.8	5.6	NS	6.2
erial (Log	Non-Vaccinated Controls	SDPC	4.2	3.8	5.5	NS
ecal Mat	า-Vaccina	4DPC	2.4	1.5	3.2	3.5
r From Fe	Nor	3DPC	<1.5	<1.5	<1.5	<1.5
CPV Titer From Fecal Material (Log FAID ₅₀ /mg Feces)		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	<1.5
	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
	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	<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	<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	<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	<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	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	

DPC – Days Post Challenge

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16 17 18 18 20 22 23 23	16 17 18 18 20 22 23	16 17 18 18 20 20	16 17 18 17 18 18 18 18 18 18 18 18 18 18 18 18 18	16	16	16	5	17	14	13	10	8	7	6	5	4	S	2	_	Dog ID -2		21	21	19	11	9	Dog ID -2		
181 181 32 23 23 8 8 8 16 45	181 181 23 23 23 8 8 8 16 16	181 181 32 23 23 8 8 8 16 45	181 181 32 23 23 8 8 8 16	181 181 32 23 23 8 8	181 181 23 23 23 32	181 32 23 23	181	181	181	021	30	512	1448	1024	2048	153	54	64	91	-24DPV1		0	2	23	91	724	-24DPV1		
8 11 11 11 11 11 11	8 8 8 8	11 11 23 23 11 11 11 11 11 11 11 11 11 11 11 11 11	8 32 32 11	8 6 32 23	32 11 6 8	108	6 8	8		6	45	32	6	23	45	64	45	32	32	0DPV1		٥	, ==	64	4	8	0DPV1		
11 23 19 4 4 4	11 8 4 19 23 11	11 23 19 8	11 23 4	11 23 19	23	11		2	16	6	64	8	4	23	16	23	23	23	8	7PV1		0	, 0	23	ω	4	7PV1		
2 2	2	ذ	<2	<2	<2	5	2	<2	2	<2	2	<2	<2	<2	<2	<2	2	<2	<2	28DPV1 (0DPV2)	Vaccinates	2>	2	<2	<2	<2	28DPV1 (0DPV2)	Non-Vaccinated Controls	Serum Neutrlization Titer
1024		1448	4	724	512	<2	<2	512	<2	45	<2	<2	1024	<2	45	724	1024	362	1024	41DPV1	es	22	2	<2	<2	<2	41DPV1	Controls	tion Titer
10004	1638/	NO TEST	8192	8192	23170	11585	9767	11585	2896	2048	11585	2896	8192	512	4096	19534	5793	6871	11585	56DPV1		^2	<2	<2	<2	<2	56DPV1		
	23170	16384	11585	16384	11585	8192	11585	11585	4884	5793	11585	11585	8192	2896	8192	23170	5793	16384	11585	70DPV1		2>	2	<2	<2	<2	70DPV1		
	16384	11585	8192	11585	11585	16384	23170	16384	11585	8192	11585	=>46341	=>23170	9767	23170	=>46341	6871	16384	=>23170	84DPV1 (0DPC)		2>	2	<2	<2	<2	84DPV1 (0DPC)		

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7417	ODPC:	IDPC	3DPC	3DPC	Non-Vacci	Non-Vaccinated Controls	1	ヿ	TDPC	\dashv	&DPC
Dog ID	107 O	102 O	2DPC	3DPC	4DPC	SDPC 104.6	6DPC	$\neg \vdash$	7DPC	7DPC 8DPC	╫
= 4	102.6	102.9	102.6	102.6	103.1	103.4	102.8	\neg	102.2	_	101.3
19	102.5	102.8	102.1	102.3	101.9	103.8	102.3	\rightarrow	102.4		101.6
21	102.2	102.3	101.3	101.4	102.0	103.4	102.0	\rightarrow	101.8	\vdash	101.5
27	102.2	102.1	102.1	102.7	102.5	102.8	103.0		102.4	Н	100.9
					Vac	Vaccinates					
Dog ID	0DPC	1DPC	2DPC	3DPC	4DPC	SDPC	6DPC		7DPC	7DPC 8DPC	\dashv
1	101.9	102.0	101.9	101.9	101.7	102.0	101.5		101.9	101.9 101.3	-
2	102.7	103.5	103.1	103.1	103.5	102.3	103.1		102.9	-	102.4
ယ	103.0	103.0	102.5	102.2	102.7	102.7	103.1	ll	103.0	\dashv	102.1
4	101.6	102.4	102.3	102.1	102.4	102.1	103.4		102.7	\dashv	102.1
5	103.5	103.4	103.2	103.3	103.5	102.6	102.8		103.4	103.4 102.8	102.8
6	102.7	102.6	101.7	102.8	102.4	102.4	102.8	ll	102.7		102.2
7	101.7	102.5	102.5	103.3	103.0	103.1	103.1		103.1		102.9
8	102.7	102.9	102.5	102.4	102.6	102.2	102.2		102.5		101.7
10	103.1	103.3	102.3	102.8	103.0	102.5	102.2	l	102.7		102.8
3	103.0	102.5	102.8	102.2	103.2	102.6	102.7	1	103.0	103.0 102.4	102.4
14	102.3	102.8	102.4	102.4	102.7	102.4	102.6	1	102.4	+	102.0
15	102.5	102.7	102.3	102.0	102.8	102.2	102.4	1	102.4	\vdash	101.9
16	101.7	102.5	102.8	101.9	102.5	102.1	102.1	1	101.9	\vdash	\vdash
17	101.9	102.8	102.3	102.6	102.7	102.1	102.0		101.9	101.9 102.0	102.0
18	102.2	102.5	102.1	101.5	102.3	102.6	102.0		102.0		101.9
20	102.2	101.9	101.9	102.0	102.2	101.8	101.8		101.9	101.9 101.6	101.6
22	102.7	102.9	102.4	101.8	102.8	102.5	102.5		102.8		102.0
23	102.5	102.8	102.7	102.7	103.2	102.4	102.7		103.1		102.1
24	103.3	103.1	102.6	102.2	102.5	102.4	102.2		102.2	102.2 102.1	
5	102.2	102.1	102.0	102.4	102.2	102.2	102.0		102.0	102.0 101.8	

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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	
		s1.5	s1.5	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	0DPC		≤1.5	≤1.5	s1.5	≤1.5	≤1.5	0DPC	
>1.5 log® FALD@/mL	≤1.5	s1.5	<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	s1.5	≤1.8	≤1.5	1DPC	
56 m L	≤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	≤1.5	2DPC		≤1.5	≤1.5	s1.5	≤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	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	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	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	
	≤1.5	s1.5	s1.5	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	8DPC		5.2	≤2.8	4.2	≥8.6	≥9.2	8DPC	
	≤1.5	s1.5	s1.5	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	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 u	p to 6 weeks of ag	ge		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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