

## **Summary of Studies Supporting USDA Product Licensure**

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	4637.24
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)	Canine Imuno-Vax 9 - No distributor specified Canine Spectra 9 - Peak Marketing Solo-Jec 9 - No distributor specified
Date of Compilation Summary	September 01, 2020

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

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Study Type	Efficacy														
Pertaining to	Infectious Canin	ne Hepatitis Viri	ıs												
Study Purpose	To demonstrate (ICH)	effectiveness ag	gainst Infectious C	anine Hepatitis											
<b>Product Administration</b>	Two doses were	administered st	ubcutaneously (SC	2) 21 days apart											
Study Animals			pies, seronegative												
	-	_	oup of 11 SC vacci	nates and one											
	group of 6 contr														
Challenge Description	•	Infectious Canine Hepatitis Virus. Puppies were observed for 21 days after challenge for clinical													
	21 days after second vaccination all dogs were challenged with Infectious Canine Hepatitis Virus.  Puppies were observed for 21 days after challenge for clinical signs.  The study was satisfactory per the criteria in														
Interval observed after	Puppies were observed for 21 days after challenge for clinical signs.														
challenge	Puppies were observed for 21 days after challenge for clinical signs.  The study was satisfactory per the criteria in														
Results	Puppies were observed for 21 days after challenge for clinical signs.														
	signs. The study was satisfactory per the criteria in														
	_														
		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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Dog	Treatment	ODPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC 7	7DPC	SDPC	9DPC 10DP	11DP	12DPC	13DPC	14DPC	15DPC 161
1	Control					22	N/A									
Dog   Treatment   ODPC   IDPC   2DPC   3DPC   4DPC   5DPC   6DPC   7DPC   8DPC   9DI																
3	Control				3,13,23**	1,3,23,22***	N/A					NI A				
4	Control				23**	1,3,7	1,3,6,7,17,20,22***					IVA				
5	Control			23*	3	22	N/A									
Dog   Treatment   ODPC   IDPC   2DPC   3DPC   4DPC   5DPC   6DPC																
19	SC Vac															
20	SC Vac															
21	SC Vac															
22	SC Vac														6	
23	SC Vac						SDPC									
24	SC Vac										6					
25	SC Vac				SDPC											
26	SC Vac					22 N/A 1,4,7,20 1,3,5,6,15,17,20,22*** 13,23** 1,3,7 1,3,6,7,17,20,22*** 3 22 N/A 7 22 N/A 6 - Serous ocular discharge 7 - Mild/Moderate mucopurulent Ocular Discharge 13 - Vomiting  22 N/A 1,4,7,20 1,3,5,6,15,17,20,22*** N/A 1,3,7 1,3,6,7,17,20,22*** 0										
27	SC Vac															
28	SC Vac															
29	SC Vac	Control   22							6						6	
	1 - Depressi	on/Letl	nargy			6 - Serous oc	ular discharge	1	5 - Exc	essive	Salivation		23 - Ot	her		
	3- Dehydrat	on				7 - Mild/Mod	derate mucopurulent	1	7 - Icte	eric Gu	ıms		* Icteri	c Luml	oar only	
	4 - Mild/Mo	Treatment		arge	2	0 - Pet	echial	Pain /		** Icte	ric lum	bar and	ears			
	5 - Severe Co			8	E	cchym	otic			***- m	oribun	d and e	uthanizati			
Dog   Treatment   ODPC   IDPC   2DPC   3DPC   4DPC   51		aroup after 16DPC	2	2 - De	ath			DPC - D	ays po	st challe	nge					

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

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	10DPC 11DPd12DPd13DPd14DPd15DPd16DPd17DPd18DPd19DPd20DPd21DPd						1		1											1 1					pava
	18DPC	L					1													1					Blank - No Clinical signs observed
	C17DPC	L																							al sign
	C16DP	L							1				L							1				ance	Clinica
	C15DP	L	L			L		1,2	1				L						L					7-Inappetance	k - No
	C14DP	L							1				L											7-Ina	Blan
e e	C13DP	L				L		1,2			L		L							-					
allen.	C12DP	L							1		1		L												argy
충	11DP	L											L												n/leth
d Po	10DPC			1				2,4	1											-1				guir	ression
serve	9DPC	2	2	1	2	1	1	1	1	4	1,2	1									1,2			5 -Retching	6 - depression/lethargy
ns Of	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				
W2 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			guiz	hing
8	SDPC	-	1	1	1,2	1		1	1,2		1				1					1	1			3- Sneezing	4 - Coughing
	4DPC	Г				Г	2	П	1		1	2	Г		П				Г	1					1
	ЗОРС	Г				Г		П	1,2				Г						Г					u	
	2DPC	Г							1,2				Г							1				scharg	charge
	1DPC								1											1				llar Di	al Dis
	ODPC 1DPC 2DPC 3DPC 4DPC																							1 - Ocular Discharge	2- Nasal Discharge
	Group	Control	Control	Control	Control	Control	SC	SC	SC	SC															
DPC - Day	Dog	_	2	L	4	2	9	7	00	6	10	11	23	24	25	26	27	28	53	30	31	32	33		

DPC - Days Post Challenge

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	21DPC				≤1.63											<1.63									
	20DPC .	Г																							
	19DPC	Г								51.83		51.63													
	18DPC	Г																			Г				
	17DPC	Г										51.63													
	100PC 110PC 120PC 130PC 140PC 150PC 160PC 170PC 180PC 190PC 200PC	Г																							
	15DPC		51.83									≤1.63							≤1.63				≤1.63		
)0uL)	14DPC			2.17							<1.83	51.63													
) <sub>50</sub> /1(	13DPC										2.5	51.83					≤1.63		<1.63		£1.63				
CAV2 Isolation from Nasal Swab Samples (TCID <sub>50</sub> /100uL)	12DPC										2.38	51.63													
mple	11DPC				≤1.63						<1.63														
/ab Sa	10DPC																	s1.63							
sal Sw	SDPC 9DPC																								
m Na	8DPC																								
on fro	7DPC	51.83	2.17		2.35	\$2.63	3.63	≤1.83								2.63									
solatic	6DPC	3.5	3.83	3.38	4.31	3.6	3.63	4.5	3.17	4.38	3.5	4.38										2.5			
AV2 Is	SDPC	3.63	3.5	4.17	3.38	4.38	4.5	4.5	3.63	2.83	3.63	4.5		2.38								2.63			
٥	4DPC	2.5	2.83	3.5	2.63	2.6	≤1.83	2.75	2.83	2.83	2.17	2.5			51.63				≤1.83			<1.83			
	3DPC	2	2	51.63		2.38	51.83	\$1.63	2.38	51.63	\$1.63	51.83							2						
	2DPC	L																						ъ	
	1DPC	L												51.6			≤1.63					\$1.6		etecte	nge
	ODPC																							titerd	Challe
	Group	Control	SC	SC	SC	SC	SC	SC	SC	SC	SC	SC	SC	Blank - No CAV2 titer detected	DPC - Days Post Challenge										
	Dog	1	2	m	4	2	9	7	00	6	10	11	23	24	52	26	27	28	53	30	31	32	33	Blank	DPC-

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Study Type	Efficacy
Pertaining to	Leptospira canicola
Study Purpose	To demonstrate effectiveness against Leptospira canicola 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
	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
challenge	clinical 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.
	A 1
	A dog was considered to have leukopenia if the platelet count
	dropped below 6 k/μL and the count was less than 50% of the baseline value.
	vascinic value.
	See the next page for data.
	see the next page for data.
USDA Approval Date	April 3, 1998
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		21DPC											П							
		100PC   11DPC   12DPC   13DPC   14DPC   15DPC   17DPC   18DPC   19DPC   20DPC   21DPC		ŋ	8								П							
		19DPC	Г		60			П		Г		Г	П							
		18DPC				ဖ								9						
		17DPC							AG					lleng	0					
		16DPC				ဗ							±	DPC = Day post-challenge						
		15DPC			A	AG			A					av po						
		14DPC							4					C = D						
		13DPC												)dQ						
		12DPC																		
llenge		11DPC																		
st Cha		100PC				⋖							Ц							
erved Po		9DPC									9								peneg	
Signs Obs	SC Vaccinates	8DPC												.0-103.9 <sup>4</sup> F)	.0-104.94F)	.0-105.9 <sup>4</sup> F)			ical signs o	
cola Clinical	SCV	7DPC									9			N1 - Fever (103.0-103.9 <sup>2</sup> F)	N2 - Fever (104.0-104.9 <sup>1</sup> F)	N3 - Fever (105.0-105.9 <sup>1</sup> F)	N4 - <99.6°F	P - Death	Blank - no clinical signs observed	
Leptospira canicola Clinical Signs Observed Post Challenge		OPC				9						Ą						( 0		
Lep		SDPC									9	9		G - Ocular Discharge Mucoid	H - Nasal Discharge Serous	<ul> <li>Nasal Discharge Mucoid</li> </ul>	J - Diarrhea Mild (loose stool)	K - Diarrhea Severe (bloody stool	ė	
		4DPC						9	٧		9			G - Ocular Dis	H - Nasal Disc	I - Nasal Disch	J - Diamhea M	K - Diarrhea Se	L - Bloody Urine	M - Icterus
		3DPC						g				g						derate		
		2DPC					9				9	AD				hing	D - Depression/Lethargy	E1 - Conjunctivitis Mild/Moderate	E2 - Conjunctivitis Severe	F- Ocular Discharge Serous
		1DPC		٨	A	٥	٥					٧		etance	90	d Breat	ession/	unctivit	unctivit	r Discha
		ODPC				ဖ			g		ŋ	g		A-inappetance	B-Vomiting	C-Labored Breathing	O - Depr	1-Con	2-Con	- Ocula
		Dog	12	13	14	15	16	17	18	19	20	71	22			_				

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yed Post Challenge		9DPC   10DPC   11DPC   12DPC   13DPC   15DPC   15DPC   17DPC   13DPC   19DPC   20DPC   21DPC	ф	d	D   A,D,NI D   G	A,0 G D,G B	A A,G	d	d	9 9	d	d	3 S,K,L A,K G G G G,L A,G G	A,D,G,K,L A,K G,K G,K	DPC = Day post-challenge					ned	
Leptospira canicola Clinical Signs Observed Post Challenge	Controls	8DPC			A	A,D,K				G,K			A,D,G,K,L A	A,D,G,L,N1 A	.0-103.9°F)	.0-104.9°F)	.0-105.9°F)			Blank - no clinical signs observed	
	3	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 clin	
tospira cani		SOPC		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					(10		
Lep		SDPC		A,D,G		0	A,N1	A,D,G,K,L,M,N4	D,G,K,L,N4	G,K	D,G,K,L,N4	D,K,L	A,B,J	9	harge Mucoid	arge Serous	arge Mucoid	J - Diarrhea Mild (loose stool)	K - Diarrhea Severe (bloody stool)	au	
		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	A	A	J,K		G,K	9	A,G,N1	A,G,N2				Ì			
		2DPC		D,G,N3	N2	D,G,N1	NI	GN2	D,N2	N2	N2	N1	G,N2	A,N1			Build	ethargy	E1 - Conjunctivitis Mild/Moderate	E2 - Conjunctivitis Severe	F- Ocular Discharge Serous
		1DPC				A,G		A		9			9		etance	in g	C-Labored Breathing	D - Depression/Lethargy	junctiviti	junctiviti	r Discha
		ODPC									H		9		A-inappetance	<b>B-Vomiting</b>	C-Labor	D - Depi	E1-Con	E2-Con	F- Ocula
		Dog	23	24	25	26	27	28	29	30	31	32	33	34							

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		14DPC	16.6	9.1	15.7	9.4	10.5	12.3	17.6	13.4	12.7	21.7	11.5
		13DPC	19.6	9.7	23.2	10.2	10.8	6.6	17.2	12.3	7.6	14.7	11
		120PC	17.2	10.2	14	9.2	10.1	10.3	11.7	7.3	9.3	13.2	9.2
		11DPC	10.7	12.7	15.3	13.1	9.3	9.5	11.6	89	13	16.5	10.2
		100PC	19.3	80	16.9	8.5	11.3	80	9.1	7	7	11.7	7.7
Challenge		90PC	19.4	10.4	19.3	8.5	6.7	7.3	9.3	8.2	11.4	14.9	11.7
Leptospira canicola White Blood Cell Count Post Challenge		8DPC	16.5	11.8	19.2	11.8	11.4	9.8	9.3	6.4	10.5	20.7	8.3
od Cell Co	inates	70PC	20.7	12.5	17.4	13.1	9.4	12.5	9.7	7.5	9.2	13.4	7.3
White Blo	SC Vaccinates	6DPC	20	00	13.6	12.2	10.2	13.2	11.7	7.2	6	13.9	11
canicola		SDPC	19.3	6	15.5	11.5	10.1	10.7	9.4	9.9	00	14.1	12.7
eptospira		4DPC	20.3	10.5	14	8.2	8.4	12.2	10.2	8.4	7.6	14.6	9.5
ĭ		3DPC	17	9.6	12.9	12.7	7.6	11.8	10.1	9.1	9.1	15.1	12.1
		20PC	15.1	9.3	12.3	9.6	9.5	12.8	10.6	00	10.7	9.5	9.4
		1DPC	25.8	12.4	19.8	80	13.2	16.1	11.4	8.4	15.8	10.5	15.6
		Baseline (Avg2DPC, -1DPC, 0DPC)	22.1	12.3	21.7	13.3	14	14.3	11	8.9	11.2	11	10.2
		Dog	12	13	14	15	16	17	18	19	20	21	22

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

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														$\neg$
		140PC			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
		120PC			26.2	11.5	15			12.69			26.3	15.7
		11DPC			36.7	9.6	13.9			9.2			31.5	10.9
a		10DPC			36.6	16.6	11.3			11.4			20.5	15.3
Challeng		9DPC			28.1	13.8	7.9			8.7			22.8	17.3
eptospira canicola White Blood Cell Count Post Challenge		80PC			26	11.7	16.2			10.4			22.8	12.6
od Cell C	Controls	7DPC		20.5	17		21			11.1			13	12
White Blo	Cont	OPC		14.6	13.6	8	19.4	13.2	17.5	10.6		15.8	8.7	9
canicola		SDPC		15.6	12.6	6.7	8.6	19.4	5.3	7.9	10.3	6.6	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
_		3DPC	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	6.7	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	22	28	29	30	31	32	33	34

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

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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	208	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		9DPC	631	470	969	497	512	288	483	476	662	581	597	
Leptospira canicola Platelet Counts Post Challenge		8DPC	478	595	693	576	655	314	463	379	704	650	473	
let Counts	cinates	7DPC	582	636	604	633	558	351	247	375	206	514	469	
ola Platel	SC Vaccinates	6DPC	531	467	497	612	555	389	542	376	538	441	517	
pira canio		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	
		20PC	480	559	452	381	409	247	356	353	497	354	455	
		10PC	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	
		Dog	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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		14DPC	O	Q	717	588	435	O	O	551	Q	Q	714	564		
		13DPC	O	O	810	590	428	O	O	969	O	O	726	475		
		120PC	D	D	738	599	528	D	D	632	D	D	701	479		
		11DPC	O	O	823	648	552	D	D	504	O	O	744	383		
		10DPC	O	O	714	721	492	D	D	269	O	O	417	310		
llenge		9DPC	O	O	710	441	455	D	D	518	O	O	235	273		
Leptospira canicola Platelet Counts Post Challenge		8DPC	Q	Q	497	302	405	0	O	412	Q	Q	87.1	142		
let Count	Controls	7DPC	0	207	285	ND	157	D	D	242	D	D	11.4	82.8		
cola Plate	Con	60PC	Q	123	160	194	100	11.3	42.2	122	O	44.1	2.4	6.8		
pira canio		SDPC	Q	45.3	117	172	49.9	11.1	15.8	81.6	14	14.2	8.5	8.3		
Leptos		4DPC	7.7	40.5	134	150	55	3.9	37.6	61.7	38	33.3	67.1	41.6		
		3DPC	11	64.1	187	196	119	45.9	195	107	80.2	103	115	64.5		
		20PC	148	161	213	279	225	60.4	305	167	150	195	182	150		
		1DPC	238	204	267	278	281	209	521	292	327	329	409	174		
		Baseline (Avg -2DPC, -1DPC, 0DPC)	300	342	519.7	404.7	482.7	242.3	529.7	329.3	432.7	395.7	563.7	232.7	ata	
		Dog	23	24	25	26	27	28	29	30	31	32	33	34	ND= No Data	D = dead

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

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Study Type	Efficac	У													
Pertaining to	Leptos	pira	grip	pot	yph	osa									
Study Purpose	To den				fecti	iven	ess	agai	nst .	Lepi	tospir	a grip	potyp	<i>hosa</i> in	
	6-week														
<b>Product Administration</b>	Two do														
Study Animals	Twenty of 10 S	•	/			-							to one	group	
Challenge Description	Fifteen												were		
Chancinge Description	challen	,	*	•											
Interval observed after	Dogs v														
challenge	2082	. 010	002												
Results	Efficac	-								-	iroche	etemia	in		
	vaccina	ates	whe	en co	omp	are	d to	con	trols	S.					
	T4					1.4.	1 1			41					
	Leptos	_				nate	a in	any	OI	tne v	accir	iates r	eceivi	ng	
	vaccine	e by	SC	rou	ie.										
	Leptos	nira	was	siso	late	d fr	om 1	ปกก	d co	ollec	ted fr	om do	os in	the	
	control												_		
	for Day	_	-				•						8		
	Dog	Dog         0         3         4         5         6         7         8         9         10         11         12         13         14           1         +         +         +         +         +         +         +         +         -<													
	1	1 + + + +													
	2	1 + + + + + 3 + + + + + 1													
	2 + + + + 3 + + +														
	4	2 + + + + 3 + + +													
	5				+	+	+								
	6						+	+	+	+	+	NA	NA	NA	
	7				+	+	+	+	+	+	NA	NA	NA	NA	
	8					+	+	+	+	+	+	NA	NA	NA	
	9				+	+	+	+	+	+	+	NA	NA	NA	
	10					+	+	+	+	+	+	NA	NA	NA	
	NA is Ar	nima	l Dea	d or	euth	naniz	ed/	no sa	ampl	e tak	en				
	+ is Posi	tive	for L	epto	spira	<b>a</b>									
HCD A A DD A	T	. 10	1.04	00											
USDA Approval Date	January	y 12	, 19	99											

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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
challenge	clinical 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/ $\mu$ L and the count was less than 50% of the baseline value.
	A dog was considered to have leukopenia if the platelet count dropped below 6 k/ $\mu$ L and the count was less than 50% of the baseline value.
	See the next page for data.
<b>USDA Approval Date</b>	March 31, 1998

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		26																
		210		H	<u></u>							Н						
		DPC 200		H				A				Н						
		DPC 19			0	0				0		Н						
		7DPC 18			w							Н						
		50PC 17										ш						
		5DPC 1										Н						
		4DPC 1										Н						
		100PC 110PC 110PC 130PC 140PC 150PC 150PC 170PC 130PC 190PC 200PC 210PC		Г				Г										
		120PC					٥					П						
nge		11DPC										٥						
Challe		100PC																
rved Post		9DPC															perved	
igns Obse	SC Vaccinates	8DPC				ų.	E							e.	분		ical Sign obs	
ero Clinical S	SCV	7090												K - Bloody Unine	L - Fever >103.0°F	M - Death	Blank - no clinical Sign observed	
Leptospira Ictero Clinical Signs Observed Post Challenge		9090	A			F					E	0					(loots	ol)
3		SDPC			٥							0		large Serous	harge Mucoid	id (loose stool)	I- Diarrhea Moderate (Watery stool)	J - Diarrhea Severe (bloody stool)
		4DPC												F - Nasal Discharge Serous	G - Nasal Discharge Mucoid	H- Diarrhea Mild   loose	I- Diarrhea Mo	J - Diamhea Se
		3DPC				ш						۵						70
		2DPC										٥				thargy	e Serous	e Mucoi
		DPC					ĄE					Н		ance	be	sion/le	Dischar	Dischar
		00PC 1DPC										H	١.	A-inappetance	B-Vomiting	C - Depression/Lethargy	D- Ocular Discharge Serous	E - Ocular Discharge Mucoid
		Dog	11	12	13	14	15	16	17	18	19	30		4	æ	3		ш

DPC = Day post-challenge

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		2																	
		C 21D												Щ		-			
		20DP											L	Ц		L			
		19DPC		ш	w														
		<b>18DPC</b>			ш						0		٥	80					
		17DPC			ш														
		16DPC			ш								п	П					
		SDPC							0					П					
		4DPC 3						Г						П		T			
		100PC   110PC   120PC   130PC   140PC   150PC   160PC   170PC   180PC   190PC   200PC   210PC																	
		2DPC 1			ш			Г	m					П					
90		1DPC 1											m	П		T			
hallen		ODPC 1								Σ		M		П					
ost C														Н		H			
erved F		9DPC		80														served	
s Obse	ols	8DPC							A									Blank - no clinical Sign observed	
al Sign	Controls	~												Н	Line	103.0°F	_	clinica	
Clinic		7DPC							_						K-Bloody Urine	L-Fever >103.0°F	M · Death	ank - no	
ctero														Н	ż	<u>.</u>	Σ	<u></u>	
Leptospira Ictero Clinical Signs Observed Post Challenge		6DPC	A										A	ш				0	
Lept								$\vdash$						Н		ъ	(100	eny sto	Stool
		SDPC							ш		0				Serous	Muco	oose st	te (Wat	(poold)
														Ц	scharpe	scharg	PIM	Modera	Severe
		4DPC	ււ	u_					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)
		2				_		$\vdash$				0		Н	ı.	Ġ	±	_	
		3DPC			_	_			٥	×		L,D	u	Ц	_	-		Sno	pio
		2DPC			_	_			_	L,E	_		_				ethargy	arge Ser	arge Mu
		10PC													tance	50	Ssion/	r Discha	r Disch
		00PC 10PC												П	A-inappetance	B-Vomiting	C - Depression/Lethargy	D- Ocular Discharge Serous	E - Ocular Discharge Mucoid
		Dog	21	22	23	24	25	36	11	38	53	30	31	32					
						_		I											

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	80.00	8.1
		120PC	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		90PC	8.5	8.6	8.3	00	7.5	7.7	7.6	00	8.2	8.7
Leptospira ictero White Blood Cell Count Post Challenge		8DPC	6.4	11.1	9.6	11.8	60	10.1	11.4	7.4	7.5	9.1
od Cell Cou	inates	7DPC	6.4	8.2	9.2	7.3	10.2	8.4	9.4	8.4	10.5	6.4
/hite Bloo	SC Vaccinates	бррс	6.4	15.2	8.8	9.3	11.2	9.4	10.5	7.1	6.7	14.4
a ictero M		SDPC	10.1	12.4	14.2	11.3	8.3	9.1	7.2	7.3	8.7	14.8
Leptospira		4DPC	6.8	9.1	9.1	12.6	00	8.1	7.5	9.9	11.7	11.9
		зорс	7.9	8.9	13.2	8.2	6	6.8	8.1	9.1	11.7	9.1
		2DPC	12.4	10.4	9.6	12.6	9.8	9.5	7.8	10.5	8.4	5.3
		1DPC	7.3	13.9	15.4	7.6	11.4	89.00	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
		Bog	11	12	13	14	15	16	17	18	19	20

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

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			Leptospira ictero White Blood Cell Count Post Challenge	a ictero V	Vhite Bloc	od Cell Co	unt Post (	Challenge					
					Cont	Controls							
1DPC 2DPC	2DPC	3DPC	4DPC	SDPC	6DPC	70PC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
9.6 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
8.5 9.3	9.3	8.2	6.5	7.3	13.4	9.4	7.2	8.2	13.4	10.1	7.7	9.7	9.4
12.2 9.4	9.4	11.6	7.1	6	10	7	6.5	7.1	11.9	7	9.6	11	11.8
19.6 10.6	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
13.9 8.5	8.5	6.9	9.1	7	10.9	12.8	9.6	10	13.9	9.4	8.3	6	7.1
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
7.5 9.4	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
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
6.7 5.8	5.8	4.1	26.4					O	•				
7.6 5	2	7.2	7.8	7.5	7.8	6.2	6.6	8	10.3	10.1	6.6	9.4	9.6
8.1 8.3	8.3	4.2	19					O	•				
9.3 6.2	6.2	5	10.7	12.6	10.6	13.5	14.5	9.6	14.1	6.6	10	10.1	9.3

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

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		14DPC	359	517	349	281	369	294	381	287	352	378	
		13DPC	471	461	337	351	290	284	373	391	406	340	
		12DPC	536	473	347	263	401	286	498	283	331	325	
		11DPC	586	453	415	330	288	258	417	388	383	501	
		10DPC	591	487	522	431	388	316	529	406	356	488	
allenge		9DPC	442	505	508	331	285	253	436	424	489	358	
Leptospira ictero Platelet Counts Post Challenge		8DPC	488	480	416	376	314	281	513	327	378	392	
Counts	nates	7DPC	447	435	517	335	400	268	457	419	200	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	Г
ptospira		4DPC	440	428	424	457	275	264	332	397	529	525	
Lej		3DPC	476	447	560	349	286	217	386	392	552	483	
		2DPC	619	456	425	413	297	298	400	569	386	506	
		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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				Leg	Leptospira ictero Platelet Counts Post Challenge	ictero	Platelet	Counts	Post C	hallenge	4				
							Controls	ols							
Dog	Baseline (Avg2DPC, -1DPC, 0DPC)	1DPC	2DPC	зорс	4DPC	SDPC	6DPC	7DPC	8DPC	ЭРС	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	859	451
25	566	401	220	146	189	288	483	611	458	466	099	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					ו	O				
30	421.9	204	80.9	53.9	119	231	379	512	549	516	642	464	411	421	427
31	319.3	163	94.4	36.7	11.9					ו	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	Efficac	y														
Pertaining to	Leptos	pira	por	non	a											
Study Purpose	To den	ons	trat	e ef	fect	iven	iess	aga	inst	Lep	otos	pira	poi	mon	a in	6
	week o															
<b>Product Administration</b>	Two do															apart
Study Animals	Twenty															
	Leptos									_	-	of o	ne g	grou	p o	10
	SC vac												11			
Challenge Description	Twenty		`		•								all a	nım	als	were
	challen												ı		.1	1
Interval observed after	Dogs v					•			•				_	•		1
challenge	sample							_								
Results	Efficac vaccina	•								-	ono	cnet	.emi	ia in		
	Vaccina	nes	WII	en c	omp	are	a to	COL	uroi	S.						
	Leptos	nira	wa	s no	t isc	late	d fr	om	hlo	od i	กลท	W O	fthe	- V2(	cin	ates
	receivi								010	<i>J</i> <b>u</b> 1.	ii ai	iy O	l tiiv	va	20111	1105
		-5 ·			<i>-</i>	, ,	Our									
	Leptos	oira	was	s isc	late	d fr	om	bloo	od c	olle	cted	l fro	m č	logs	in t	he
	control													_		
		_														
	for Days 0 – 14 (post-challenge):    Dog															
	1 + + + + 2															
	1 + + + + 2															
	4				+	+										
	5			+	+	+	+									
	6			+	+											
	7		+	+	+											
	8			+	+	+										
	9		+	+	+	+										
	10		+		+	+										
	+ is Pos	tive	for L	.eptc	spir	a	1	1	I	1	1		I	1	I	
					•											
<b>USDA Approval Date</b>	Januar	/ 12	, 19	99												

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

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## CPI Serum Neutralization Antibody Titers

					Controls					
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

					SQ Vaccinat	es				
Dog	0DPV1	14DPV1	0DPV2	7DPV2	14DPV2 (w)	14DPV2	21DPV2	7DPC	14DPC	21DPC
20	<2	<2	<2	<2	10	36	42	1248	7281	6295
21	<2	<2	<2	<2	3	16	6	2892	5880	4742
22	<2	<2	<2	<2	<2	18	6	1446	7037	3622
23	<2	<2	<2	<2	4	46	10	1152	10809	4581
24	<2	<2	<2	<2	<2	3	3	1579	4562	4096
25	<2	<2	<2	<2	<2	<2	<2	811	2884	10139
26	<2	<2	<2	<2	<2	<2	<2	227	793	661
27	<2	<2	<2	<2	<2	27	12	789	7079	5754
28	<2	<2	<2	<2	<2	<2	4	878	2253	2655
29	<2	<2	<2	<2	<2	16	5	1330	9462	7228
30	<2	<2	<2	<2	<2	3	3	373	1151	724
31	<2	<2	<2	<2	<2	<2	<2	2048	2281	2586
32	<2	<2	<2	2.2	<2	<2	3	1833	1193	880

DPV - Days Post Vaccination

DPC - Days Post Challenge

A titer of <2 is considered seronegative

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## **CPI Virus Isolation from Nasal Swabs**

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

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

<sup>–</sup> means CPI virus was not detected

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<sup>+</sup> means CPI virus was detected

Study Type	Efficacy											
Pertaining to	Canine Distemp	er Virus (CDV)	)									
Study Purpose	To demonstrate	effectiveness ag	gainst CDV									
<b>Product Administration</b>	Two doses were	administered s	ubcutaneously 21	days apart								
Study Animals	Seventeen (17) 6	-week-old pup	pies seronegative f	for CDV								
	were randomly s	sorted into 1 gro	oup of 11 SC vacci	nates and								
	one group of 6 c	ontrols.										
Challenge Description	•	ond vaccination	n all dogs were cha	allenged with								
	CDV.											
Interval observed after	•	ved for 42 days	s after challenge fo	or clinical signs								
challenge	of CDV.											
Results	The study was sa	atisfactory per t	the criteria in 9 CF	R 113.306								
	(b)(3) (i-ii)											
	_			1								
		Mortality	Clinical Signs of									
	CDV Infection											
	CDV Infection											
	Controls	5/6 (83%)	6/6 (100%)									
	See the next pag	e for data.										
<b>USDA Approval Date</b>	April 6, 1998											

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				CDV Clin	ical Signs (	Observed Po	st Challeng	CDV Clinical Signs Observed Post Challenge - Control Dogs	S		
Dog	ODPC	1DPC	2DPC	3DPC	4DPC	SDPC	6DPC	7DPC	8DPC	90PC	10DPC
			10,12,18	10,12,18	10,11,12	10	2,12	10,12,16,17,Euth	20	20	20
2				2,10,12	10	2,10,12	1,2,10,12	14	8,10,12,14,16,17,18, Euth	20	20
m				2,10,12		10,12	12	14	8,10,11,14	1,8,10,11,12	2,8,10,12
4				2,10,12		2,10,12	10	10,12	1,2,8,10,12	2,8,17	20
ιń							10,12		10,11	2,10,12	10,12
9					2,12	2,10,12	2,10,12	11,12	12,2	2,10,12	2,8,10,12
	500.	000	200	0007	1	00000	00000	00000	SC CO	0000	
Dog	11DPC	12DPC	13DPC	14DPC	15DPC	16DPC-26DPC	27DPC	28-29DPC	30DPC	31-42DPC	
	20	20	20	30	20	20	30	20	50	20	
2	20	20	20	20	20	20	20	20	20	20	
m	8,10,12	1,8,10	8,10,11	1,8,9,10,12	20	20	20	20	20	20	
4	20	2	20	20	20	20	20	20	20	20	
iñ	8,10,12,14		2,11		11,12		10,12		10,12		
ý.	1,2,8,10,12	1,2,8,12	20	20	20	20	20	20	20	20	
	1 - Depress	1 - Depression/Lethargy	<u> </u>		14 - Vomiting						
	2- Mild/Mo	od. Ocular D	2- Mild/Mod. Ocular Discharge Mucoid	pio	16 - Excessive Salivation	Salivation		Intermittent minor st	Intermittent minor stool abnormalities observed were not	ed were not	
	8 - Dehydration	ation			17 - Chewing gum fits	gum fits		considered cillical s	considered cilinical signs of CDV infection.		
	10-Mucous stoo	stool			18 - neuromuscular Tics	scular Tics					
	11-watery Stool	Stool			20 - death						
	12-Bloody stool	stool			Blank - No Ci	Blank - No Clinical signs observed	served				

DPC – Days Post Challenge

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		21DPC	10,12									12							
		ODPC   10PC   20PC   30PC   40PC   50PC   60PC   70PC   80PC   100PC   110PC   120PC   130PC   140PC   150PC   160PC   170PC   180PC   190PC   200PC   210PC									12	12		pava					
		19DPC			10							11,12	10,12	Intermittent minor stool abnormalities observed	CDV				
		18DPC										11,12		ormaliti	signs of				
		17DPC		14								10,12	10,12	ol abno	linical				
ogs		16DPC												nor sto	dered				
ted D		15DPC		Г										ttent m	ot consi	ć.			
ccina		14DPC												Intermi	were not considered clinical signs of CDV	infection.			
e - Va		13DPC																	
CDV Clinical Signs Observed Post Challenge - Vaccinated Dogs	52	12DPC																	0
ost Ch	SC Vaccinates	11DPC																	Blank - No Clinical signs observed
ved Po	SCV	10DPC													vation	fits	rTics		signs
Obser		9DPC												99	16 - Excessive Salivation	17 - Chewing gum fits	18 - neuromuscular Tics		Clinical
igns		8DPC											Ц	14 - Vomiting	xcess	hewir	euron	20 - death	k - No
cal S		7DPC											Ц	14-1	16 - 6	17.0	18-	20-02	Blan
Clini		6DPC													pid				
9		SDPC													Mucc				
		4DPC						10							harge				
		3DPC											П	hargy	or Disc				
		SDPC	Г	Г							Г	Г	П	n/Let	Ocula	uo	100	10	100
		DPC	Г		Г						Г			ressio	/Mod	ydrati	s sno	ery Sto	ody sto
		ODPC												1 - Depression/Lethargy	2- Mild/Mod. Ocular Discharge Mucoid	8 - Dehydration	10-Mucous stoo	11-watery Stool	12-Bloody stoo
		Dog	18	19	20	21	22	23	24	25	26	27	28						

DPC – Days Post Challenge

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		42DPC												ned					
		28DPC 29DPC 30DPC 31DPC 32DPC 33DPC 34DPC 35DPC 36DPC 37DPC 38DPC 39DPC 40DPC 41DPC 42DPC												Intermittent minor stool abnormalities observed	CDV				
		40DPC											12	ormaliti	were not considered clinical signs of CDV				
		39DPC												nde loc	clinical				
		38DPC					14							inor sto	dered				
S		37DPC											12	ttent m	ot cons	on.			
Clinical Signs Observed Post Challenge - Vaccinated Dogs		36DPC												Interm	were n	infection.			
nate		35DPC											12						
Vacci		34DPC											12						
nge -		33DPC											12						henri
Challe	notes	32DPC													u		57		ne ohea
Post	SC Vaccinates	31DPC													16 - Excessive Salivation	um fits	18 - neuromuscular Tics		ient ein
servec		30DPC	Г					12			10			niting	essive S	17 - Chewing gum fits	romuse	th	No Clin
ns Ob		29DPC									10		10,12	14 - Vomiting	16 - Exc	17 - Che	18 - neu	20 - death	Riank - No Clinical signs obsequed
al Sig		28DPC						10				12							
CDV Clinic		27DPC						10			10	10,11,12			P				
5		26DPC						10				10,12			e Muco				
		22DPC 23DPC 24DPC 25DPC 26DPC					10,12							AS	ischarg				
		24DPC										10,12	10,12	1 - Depression/Lethargy	cular D	_	10		
		23DPC	Г										10,12	ession	Mod. 0	dration	ous stoc	11-watery Stool	do eton
		22DPC	11					10				11,12	11	1 - Depr	2- Mild/Mod. Ocular Discharge Mucold	8 - Dehydration	10-Mucous stoo	11-wate	12-Riondy etoni
		Dog	18	19	20	21	22	23	24	25	26	27	28						

DPC – Days Post Challenge

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Study Type	Efficacy
Pertaining to	Canine Parvovirus (CPV)
Study Purpose	To demonstrate effectiveness against CPV in 6-week-old
	puppies.
Product Administration	Two doses, given at an interval of 21 days, were administered
	subcutaneously (SC).
Study Animals	Study analysis was conducted on twenty-one (21) 6-week-old
	puppies seronegative for CPV, 17 vaccinates and 4 non-
	vaccinated controls.
Challenge Description	Twenty-one (21) days after second vaccination puppies were
	challenged with CPV 2b strain.
Interval observed after	Puppies were observed daily for 14 days after challenge
challenge	
Results	The data were analyzed according to 9 CFR 113.317.
	Number affected by challenge according to 9 CFR 113.317:
	Number affected by chancing according to 9 CTR 113.317.
	Vaccinates: 0/17 (0%)
	Controls: 2/4 (50%)
	See the next page for data.
	1 21 2001
<b>USDA Approval Date</b>	August 31, 2001

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CPV Post Challenge Daily Observations

_			_			_			_	_	_	_		_	_	_	_	_	_	_				_
	14DPC						14DPC																	
	13DPC						13DPC																	
	12DPC						12DPC																	
	11DPC						11DPC							E										
	10DPC						10DPC			E		٥												
	9DРС						9DPC										D							
rols	SDPC		0				SDPC																	
ated Cont	лрРС		С	-	-	Vaccinates	лрРС																	
Non-Vaccinated Controls	6DPC	E,H	B,C,H	B,G,H	B,C,D,F,G,H	Vacc	6DPC			I														
	SDPC			٥	Н,2		SDPC											٥						
	4DPC			I			4DPC																	
	3DPC						3DPC																	
	2DPC						2DPC													O				
	1DPC	٥					1DPC											٥						
	0DPC						0DPC			٥														
	e P	1	2	ო	4		D <sub>og</sub>	1	2	3	4	2	9	7	80	6	10	11	12	13	14	15	16	17

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

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Daily Rectal Temperature (°F)

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

	14DPC	101.8	102.1	100.8	102.3	101.8	102.0	101.6	101.2	102.1	101.6	102.2	101.9	101.3	101.7	102.3	102.3	101.7
	13DPC	101.3	101.3	101.4	100.9	101.3	102.7	101.1	101.3	101.8	101.0	102.1	101.8	101.1	100.5	101.7	101.8	101.2
	12DPC	101.7	101.7	101.3	101.2	101.5	102.5	101.3	101.0	101.4	101.1	101.9	101.4	101.2	101.0	101.3	101.4	101.4
	11DPC	101.8	101.7	101.0	101.4	101.7	102.4	101.0	101.3	102.3	101.2	102.5	101.6	101.1	100.8	101.4	101.3	101.2
	10DPC	101.1	101.4	100.9	101.3	101.6	102.3	101.2	101.1	101.7	101.1	101.7	101.3	101.1	101.4	101.2	101.7	101.6
	9DPC	101.7	101.6	101.2	101.4	101.5	101.8	101.0	101.1	101.3	101.1	102.3	101.2	101.3	100.4	101.8	101.9	101.4
	SDPC	101.5	101.7	101.4	101.7	101.3	101.5	101.3	101.1	101.5	101.1	102.3	101.0	101.1	100.7	101.4	101.6	101.7
Vaccinates	7DPC	101.0	101.3	100.5	101.3	101.1	101.4	101.2	101.0	100.9	100.9	101.5	101.5	101.7	100.7	100.7	101.3	101.3
Vš	6DPC	101.0	101.5	100.6	101.3	101.3	101.1	100.8	100.9	101.1	100.6	101.8	101.3	100.3	101.5	100.8	100.9	100.8
	SDPC	101.5	101.5	101.1	101.1	101.0	101.6	100.8	101.3	101.0	101.2	102.2	101.8	101.5	101.4	101.4	102.5	101.9
	4DPC	101.7	101.1	101.3	101.4	101.2	102.0	100.9	101.1	101.2	101.2	102.1	101.4	101.0	101.0	101.6	101.8	101.2
	3DPC	101.3	101.3	100.8	101.7	101.5	101.5	101.2	101.1	101.0	101.4	101.8	101.5	101.3	101.4	101.0	101.7	102.1
	2DPC	101.2	101.5	101.0	101.4	101.4	102.1	101.0	101.5	102.1	101.6	10.2	101.4	101.8	101.0	101.1	101.9	102.0
	1DPC	101.9	100.5	100.5	100.9	101.0	101.9	100.8	100.7	101.6	100.8	101.5	102.2	100.4	101.1	101.2	102.1	101.6
	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	99.7	100.7	100.9	101.8
	Cat ID	5	9	7	8	6	10	11	12	13	14	15	16	17	18	19	20	21

DPC = Days Post Challenge

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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	5DPC	13.9	12.7	15.6	6.3
n-Vaccina	4DPC	11.2	17.0	30.2	19.9
Noi	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	9.8	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		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	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		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
CPV Titer From Fecal Material (Log FAID50/mg Feces)		7DPC	5.5	5.4	NS	NS
FAID <sub>50</sub> /I	trols	6DPC	5.8	5.6	NS	6.2
erial (Log	Non-Vaccinated Controls	SDPC	4.2	3.8	5.5	NS
ecal Mat	-Vaccina	4DPC	2.4	1.5	3.2	3.5
r From Fe	Nor	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
		ťΒ	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	5.1>	NS	<1.5	S.1>	NS	<1.5	<1.5	5.1>	S.1>	5.1>	<1.5	<1.5	<1.5	<1.5	SN	<1.5
Vacc	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
<b>Product Administration</b>	Two doses given at an interval of 28 days were administered
	subcutaneously (SC).
Study Animals	Twenty-five (25) 6-week-old puppies seropositive for parvovirus; 20 vaccinates and 5 non-vaccinated controls.
<b>Challenge Description</b>	Fifty-six days (56) after second vaccination puppies were challenged with CPV type 2c strain.
Interval observed after challenge	Puppies were observed for clinical signs daily for 14 days after challenge
Results	Dogs were determined affected by the criteria of 9 CFR 113.317(c)(3)(i).  Number affected:  Vaccinates: 1/20 (5%) Controls: 4/5 (80%)  See the next page for data.
<b>USDA Approval Date</b>	January 31, 2012

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14DPC 14DPC ğ 13DPC 13DPC 1,3 ğ 12DPC 12DPC ĝ 11DPC 11DPC ĝ 10DPC 10DPC ĝ CPV Post challenge Clinical Observations 9DPC 9DPC Blank - No clinical signs observed ğ 5 SDPC 7DPC 8DPC 2,3,4 1,3 Non-Vaccinated Controls 7DPC 1,2,3 1,2,3 Vaccinates 2,3 6DPC 6DPC 1,2,3 1,2,3 SDPC SDPC 1,2,3 1,2,3 4DPC 4DPC 3-Bloody Stool 4-Death 3DPC 3DPC 2DPC 2DPC 1 - Mucous Stool 2-Diarrhea (Watery stool) 1DPC 1DPC 0DPC 0DPC DogID Dogin 19 27 27 ω 6 ಶ

DPC – Days post challenge

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		84DPV1 (0DPC)	<2	<2	<2	<2	<2			84DPV1 (0DPC)	=>23170	16384	6871	=>46341	23170	2926	=>23170	=>46341	11585	8192	11585	16384	23170	16384	11585	11585	8192	11585	16384	0767
		70DPV1	<2	<2	<2	<2	<2			70DPV1	11585	16384	5793	23170	8192	2896	8192	11585	11585	5793	4884	11585	11585	8192	11585	16384	11585	16384	23170	11585
	•	56DPV1	<2	<2	<2	<2	<2			56DPV1	11585	6871	5793	19534	4096	512	8192	2896	11585	2048	2896	11585	2926	11585	23170	8192	8192	NO TEST	16384	Anas
ation Titer	d Controls	41DPV1	<2	<2	<2	<2	<2		Vaccinates	41DPV1	1024	362	1024	724	45	<2	1024	<2	<2	45	<2	512	<2	<2	512	724	4	1448	1024	1448
Serum Neutrlization Titer	Non-Vaccinated Controls	28DPV1 (0DPV2)	<2	<2	<2	<2	<2			28DPV1 (0DPV2)	<2	<2	2	<2	<2	<2	<2	<2	2	<2	2	<2	2	5	<2	<2	<2	<2	<2	2
		7PV1	4	3	23	10	9			7PV1	8	23	23	23	16	23	4	8	64	9	16	2	11	23	19	4	8	11	4	16
		0DPV1	8	4	64	11	8			0DPV1	32	32	45	64	45	23	9	32	45	9	8	9	11	32	23	11	11	8	11	33
		-24DPV1	724	91	23	<2	10			-24DPV1	91	64	54	153	2048	1024	1448	512	128	181	32	23	8	32	16	45	<2	2	4	128
		Dog ID	6	11	19	21	27			Dog ID	-	2	3	4	5	9	7	8	10	13	14	15	16	17	18	20	22	23	24	28

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

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10DPC 10DPC 2.13 3.35 2.60 1.98 2.38 4.78 1.67 2.33 4.83 2.59 3.30 Ř 9DPC 9DPC 2.09 2.11 2.08 2.52 2.66 1.09 2.24 1.91 2.59 2.83 4.57 3.24 2.59 3.98 2.35 1.27 2.71 8DPC 8DPC 1.36 4.18 1.52 2.92 2.87 2.32 2.51 2.64 3.24 0.93 1.34 3.01 1.67 2.27 g 7DPC 7DPC 1.66 2.03 1.49 2.65 1.04 2.04 3.23 0.22 2.23 3.22 4.10 2.90 0.27 2.41 3.27 2.57 1.97 2.51 6DPC 0.74 69.0 1.59 1.75 1.09 6DPC 3.20 2.34 2.44 3.09 3.66 3.29 3.13 3.04 3.98 1.98 2.44 1.81 2.52 3.31 1.57 Lymphocyte Counts Post Challenge (x10³/µl) 5DPC 5DPC 0.58 0.70 2.75 1.19 2.65 2.35 1.00 2.73 1.62 1.64 2.98 2.69 3.04 0.67 2.57 3.07 4DPC 4DPC 0.30 0.29 1.42 3.03 1.65 2.03 1.26 1.79 3.28 2.93 3.05 1.17 0.92 1.68 2.39 2.85 2.83 2.50 3.01 3DPC Vaccinates 3DPC 2.25 1.16 1.78 2.56 3.76 3.35 0.80 1.82 2.42 1.53 3.04 2.62 2.62 2.39 2.31 3.27 2.57 2.91 2DPC 2DPC 2.26 1.45 2.36 3.05 2.46 2.45 1.55 2.43 2.84 2.48 2.37 1.32 1.51 1.93 1.88 3.62 2.08 2.22 2.81 1DPC 1DPC 2.28 2.32 2.29 3.23 1.18 2.56 2.68 3.32 2.42 1.23 1.84 1.93 2.43 3.10 2.42 2.58 1.81 3.57 2.97 Average Average 2.13 1.27 1.86 2.43 2.46 1.67 1.21 1.99 2.94 2.48 2.39 2.09 2.00 2.41 0.91 1.92 ODPC ODPC 1.16 1.18 1.38 2.30 2.34 2.34 2.46 2.66 2.06 2.50 2.05 2.52 2.00 3.27 2.24 3.02 2.11 1.87 -1DPC -1DPC 2.14 1.20 2.26 2.50 2.40 1.59 96.0 1.89 2.25 2.24 2.30 2.54 2.14 2.82 3.06 1.84 1.22 2.11 -2DPC -2DPC 1.24 2.24 2.68 2.45 2.09 1.10 1.43 2.74 1.26 1.68 2.25 2.06 1.83 0.62 1.57 2.07 2.17 2.21 1.67 CatID CatID 18 19 9 13 7 15 16 Ξ 21 1 6 S 9 ∞

4.33 1.22 3.54 0.92

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10DPC 101.9 101.4 101.9 10DPC 102.6 101.9 102.1 101.9 101.6 102.1 101.9 101.9 101.6 102.2 101.7 102.1 102.7 102.1 102.7 101.7 ŝ 101.6 102.6 101.9 102.9 102.4 9DPC Na 101.5 102.1 101.5 9DPC 102.5 102.1 103.1 102.4 102.2 101.7 101.4 101.5 101.1 101 Na 101.3 101.6 101.5 100.9 102.1 102.2 102.2 102.9 101.7 102.8 102.4 101.9 101.5 102.0 101.9 101.6 102.0 SDPC SDPC 101.8 101.3 102.1 102.1 100.9 102.2 102.4 101.8 101.9 103.0 103.1 102.5 102.7 103.0 102.4 102.4 101.9 102.0 101.9 101.9 102.0 7DPC 102.4 7DPC 102.7 103.4 102.7 103.1 Body Temperature Post Challenge °F 103.1 102.2 102.2 102.7 102.6 6DPC 103.2 102.8 102.3 103.0 103.1 103.4 102.8 102.8 102.4 102.1 102.0 102.0 101.8 102.5 102.0 6DPC 101.5 102.7 Non-Vaccinated Controls SDPC 104.6 103.4 103.8 103.4 102.8 102.0 102.7 102.1 102.6 102.4 103.1 102.5 102.5 102.6 102.4 102.1 102.1 102.6 101.8 102.5 102.4 102.4 102.2 SDPC Vaccinates 4DPC 103.1 101.9 102.0 102.5 4DPC 101.7 102.7 102.4 103.5 102.4 103.0 102.6 103.0 103.2 102.7 102.8 102.5 102.3 102.3 102.2 102.8 103.2 102.2 103.2 102.6 102.3 101.4 102.7 103.3 102.4 102.8 102.2 102.4 102.0 101.9 102.6 101.5 102.0 101.8 102.9 101.9 102.1 103.3 102.8 102.4 3DPC 3DPC 102.2 102.7 102.5 102.5 102.3 102.0 102.6 102.1 102.1 101.3 102.1 102.8 102.1 102.1 101.9 102.4 102.7 101.9 102.5 102.3 103.2 101.7 102.8 102.4 102.3 2DPC 2DPC 102.9 102.8 102.3 103.0 103.4 102.5 102.5 101.9 102.9 102.0 102.5 102.5 102.0 102.4 103.3 102.8 1DPC 1DPC 102.7 102.1 102.1 0DPC 102.0 102.6 102.5 102.2 102.2 ODPC 101.9 103.0 101.6 103.5 102.7 103.0 102.5 101.9 102.2 102.2 102.7 102.5 101.7 102.2 101.7 103.1 Dog ID Dog ID 19 27 13 10 Ξ 2 9 ∞ 6 7 3 4

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10DPC 10DPC s 1.5 s 5.15 s 1.5 <1.5 s 1.5 <u>s</u>1.5 <u>s</u>15 9.9 3.6 В 9DPC 9DPC ≥7.6 ≤3.0 s 1.5 s 1.5 s 1.5 s 1.5 s 1.5 s 1.5 <u> 15</u> s 1.5 <u> 15</u> s 1.5 <u> 15</u> <u> 15</u> 1.5 s 1.5 s 1.5 <u> 5</u> 4.5 ğ 4 8DPC 8DPC s 5 ≥9.2 ≥8.6 ≤2.8 <u>s15</u> <u>s15</u> <u>s15</u> <u>s15</u> s 5.15 s 1.5 <u>s15</u> <u>s15</u> <u>s15</u> <u>s15</u> <u>s15</u> <1.5 21.5 4.2 7DPC 7DPC s1.5 s1.5 ≥8.5 s1.5 s1.5 s1.5 s1.5 s 1.5 s1.5 s1.5 s1.5 s1.5 s1.5 s1.5 s1.5 s 1.5 s1.5 ≤2.5 s1.5 s 1.5 9.7 6.8 5.2 Fecal Virus Isolation Titer Post Challenge 6DPC 6DPC s 1.5 <1.5 <1.5 <1.5 s 1.5 7.6 7.5 7.5 6.3 5DPC 5DPC s1.5 s1.5 s1.5 s1.5 s1.5 s1.5 s1.5 s1.5 s 1.5 s1.5 s 1.5 <1.5 <1.5 <2.5 s 1.5 s 15 s 15 s 1.5 s 1.5 9.9 7.2 4.2 4.7 5.2 Vaccinates Controls 4DPC 4DPC <2.5 ≤2.8 s 5.15 s 1.5 <u> 15</u> s 1.5 <u> 15</u> s 1.5 s 5. s 5. <u> 15</u> s 5. s 5. <u>د</u> اح <u>د</u> اخ <u>د</u> اخ <u>د</u> اخ 5.5 2.5 4.3 s1.5 3DPC <1.5 s1.5 8. 3DPC s1.5 s 1.5 <1.5 s1.5 s 1.5 s 5 s 1.5 s 5 s 1.5 s 1.5 s 5 s 1.5 s 1.5 s 1.5 2DPC 2DPC s1.5 s1.5 <1.5 s1.5 <1.5 <1.5 s1.5 s1.5 s 1.5 s1.5 <1.5 s1.5 s1.5 s1.5 s1.5 s1.5 <1.5 s1.5 <1.5 s 5. s 1.5 <u>s</u>1.5 <u>s</u>1.5 s 1.5 s 1.5 Positive For CPV >1.5 log10 FAID30/mL 1DPC s1.8 <1.5 s1.5 <1.5 1DPC ≥1.6 s 1.5 s 1.5 s 1.5 s 1.5 s 1.5 21.5 <u>21.8</u> s 1.5 s 1.5 s 1.5 <u> 5</u> s 1.5 ODPC 0DPC s1.5 <1.5 s 1.5 <u> 5</u> <1.5 <u>s</u> <1.5 s 1.5 <u>s</u>1.5 <u>s</u>1.5 <u>s</u>1.5 s 5. CatID CatID 19 10 13 14 15 16 22 22 23 23 Ξ 21 27 17 24 6 က 4 5 9  $\infty$ 2

DPC – Days post challenge

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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
	this product
<b>Product Administration</b>	_
Study Animals	
Challenge Description	
Interval observed after	
challenge	
Results	Study data are not available.

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

## **Summary of Reactions:**

		Puppies u	p to 6 weeks of a	ge		Dogs >				
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	

<sup>\*</sup>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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