

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

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	46J9.23
True Name	Canine Distemper-Adenovirus Type 2-Coronavirus- Parainfluenza-Parvovirus Vaccine, Modified Live & Killed Virus, Leptospira Canicola-Grippotyphosa- Icterohaemorrhagiae-Pomona Bacterial Extract
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Canine Imuno-Vax 10 - Aspen Veterinary Resources Ltd. Canine Spectra 10 - Peak Marketing Solo-Jec 10 - No distributor specified
Date of Compilation Summary	June 02, 2020

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

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Study Type	Efficacy													
Pertaining to	Infectious Canin	ne Hepatitis Viri	us											
Study Purpose	To demonstrate (ICH)	effectiveness ag	gainst Infectious Ca	anine Hepatitis										
<b>Product Administration</b>	Two doses were	administered s	ubcutaneously (SC	) 21 days apart										
Study Animals			pies, seronegative											
	were randomly s	sorted into 1 gro	oup of 11 SC vaccin	nates and one										
	group of 6 contr													
Challenge Description	21 days after sec	cond vaccination	n all dogs were cha	illenged 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	signs.													
challenge	The study was satisfactory per the criteria in													
Results														
	* * *													
	The study was satisfactory per the criteria in 9 CFR 113.305(1)(ii) (A)(B)													
		Mortality	Clinical Signs of CDV Infection											
	SC Vaccinates	0/11 (0%)	0/11 (0%)											
	Controls	6/6 (100%)	6/6 (100%)											
<b>USDA Approval Date</b>	March 31, 1998													

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Dog	Treatment	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC 7	7DPC 8	DPC	9DPC	10DPC	11DP0	12DPC	13DPC	14DPC	15DPC	16DP
1	Control					22	N/A		•						·	<u> </u>		
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***						INA					
5	Control			23*	3	22	N/A											
6	Control			7	7	22	N/A											
19	SC Vac																	
20	SC Vac																	
21	SC Vac																	
22	SC Vac															6		
23	SC Vac																	
24	SC Vac										6							
25	SC Vac																	
26	SC Vac																	
27	SC Vac																	
28	SC Vac																	
29	SC Vac								6							6		
	1 - Depression	on/Let	nargy			6 - Serous oc	ular discharge	1	.5 - Exce	ssive	Salivat	ion		23 - 0	ther			
	3- Dehydrati	ion				7 - Mild/Mod	derate mucopurulent	1	.7 - Ictei	ric Gu	ms			* Icter	ic Luml	oar only	,	
	3- Dehydration 4 - Mild/Moderate Conjunction		nctivitis		Ocular Disch	arge	2	0 - Pete	chial	Pain/			** Icte	eric lum	bar and	dears		
	5 - Severe Co	onjunc	tivitis			13 - Vomitin	g	E	cchymo	otic				***- n	noribun	d and e	uthani	zation
	5 - Severe Conjunctivitis			NO Clinic	al signs ob	served in any	group after 16DPC	2	2 - Dea	th				DPC - I	Days po	st challe	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.
<b>Challenge Description</b>	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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	1DPC																								
	10DPC 11DPQ12DPQ13DPQ14DPQ15DPQ16DPQ17DPQ18DPQ19DPQ20DPQ21DP																			1					
	19DPC						1		1											1					pav
	18DPC						1													1					Blank - No Clinical signs observed
	17DPC																								Isigns
	16DPC								1											1				uce	Clinica
	15DPC	L						1,2	1															7-Inappetance	oN -
	14DP(							1	1															7-Ina	Blan
e,	13DPC	L						1,2					L												
llen	C12DP(	L						1	1		-														argy
충	11DP(	L																							n/leth
d Pos	10DPC			1				2,4	1			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 Ok	8DPC	2	1,2	1	1,2,	1		1	1	4	1	1			1					1	1				
CAV2 Clinical Signs Observed Post Challenge	7DPC		1,2	1	1,2,4	1,4		1,2,4,5,6	1	1	1	1,2							1	1	1				
AV2 CI	6DPC	1,2	1,2	1,2	1,2	1	4	1,2,4	1,6	1	1	1,2						1	1	1	1			zing	hing
3	SDPC	1	1	1	1,2	1		1	1,2		1				1					1	1			3- Sneezing	4 - Coughing
	4DPC	Г					2		1		1	2								1					Ì
	ODPC 1DPC 2DPC 3DPC 4DPC								1,2											1				e S	61
	2DPC								1,2											1				1 - Ocular Discharge	2- Nasal Discharge
	1DPC								1											1				ular D	sal Dis
	ODPC																							1-00	2- Na:
	Group	Control	Control	Control	Control	Control	SC	SC	SC																
DPC - Day	s Post (	Thalle	L	m	4	2	9	7	00	6	10	11	23	24	25	56	27	28	53	30	31	32	33		

DPC - Days Post Challenge

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	DG.	П			≤1.63											<1.63									
	C 210	H	Н		12							L	_			51	L	L		L	L				
	20DP											L													
	19DPC									51.83		51.63													
	18DPC	Г										Г								Г					
	9DPC  10DPC 11DPC 12DPC 13DPC 14DPC 15DPC 16DPC 17DPC 18DPC 19DPC 20DPC 21DPC	Г										51.63													
	16DPC	Г	П	П								Г			П					Г					
	SDPC 1	Г	51.83	П								51.63							≤1.63				≤1.63		
<u>1</u>	4DPC 1	Г	-	2.17							51.83	51.63			П					Г					
<sub>50</sub> /10	3DPC 1	Г	П								2.5	51.83			П		51.63		<1.63	Г	51.63				
TCID	2DPC 1	Н	Н								2.38	51.63					VI		VI	Н	VI				
ples	DPC 13	Н	Н		51.63						51.63	VI	_							H					
Sam	DPC 11	Н	Н		Vi						vi	H						.63		H	H				
Swak	)C 10	H	Н	Н								H	_		H		H	51.		H	H				
sals	$\vdash$	Ц	Ц									L								L					
ž	8DPC											L													
n fro	7DPC	51.83	2.17		2.35	\$2.63	3.63	≤1.83								2.63									
AV2 Isolation from Nasal Swab Samples (TCID <sub>50</sub> /100uL)	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			
V2 Iso	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			
8	4DPC	2.5	2.83	3.5	2.63	5.6	51.83	2.75	2.83	2.83	2.17	2.5			51.63				<1.83	Г		\$1.83			
	-	2	2	51.63		2.38	51.83	\$1.63	2.38	51.63	51.63	51.83			П				2	Г					
	2DPC 3DPC	Г										Ī													
	1DPC	Г	П	П								r		51.6			≤1.63			Г		51.6		ected	e e
	ODPC	Г										r												iter det	hallen
	Group	Control	SC	SC	SC	SC	SC	SC	SC	SC	SC	20	SC	Blank - No CAV2 titer detected	DPC - Days Post Challenge										
	Щ	ш	Co	Co	Co	Co	S	S	Н	Ö		$\vdash$								L				nk - No	- Days
	Dog	1	2	ന	4	2	φ	7	00	σ	10	11	23	24	25	26	27	28	53	8	31	32	33	Bla	9

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

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Study Type	Efficacy
Pertaining to	Leptospira canicola
Study Purpose	To demonstrate effectiveness against <i>Leptospira canicola</i> in 6
	week old dogs.
Product Administration	Two doses were administered subcutaneously (SC) 3 weeks
	apart.
Study Animals	Twenty-three (23) 6-week-old puppies serologically negative
	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 decress considered to have lowly and it if the intertal of count
	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																			
		200PC		ŋ	8							Г	П								
		19DPC			60								П								
		18DPC	П	П		g	П	П				Г	П			٦					
		17DPC							AG				П		lleno	0 =					
		15DPC 16DPC				ŋ							±		DPC = Day post-challenge						
		15DPC			A	AG			A						av bo						
		14DPC							A						) = D						
		11DPC   12DPC   13DPC   14DPC													DPC						
		12DPC												_							
lenge		11DPC																			
St.		100PC				⋖							Ш								
erved Po		9DPC									9									pened	
Signs Obs	SC Vaccinates	8DPC													.0-103.9 <sup>4</sup> F)	.0-104.9 <sup>4</sup> F)	.0-105.9 <sup>1</sup> F)			ical signs ob	
ola Clinical	SCV	7DPC									9				N1 - Fever (103.0-103.9 <sup>4</sup> F)	N2 - Fever (104.0-104.9 <sup>4</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		50PC				9						¥									
Lept		SDPC									9	9			harge Mucoid	harge Serous	arge Mucoid	J - Diarrhea Mild (loose stool)	K - Diarrhea Severe (bloody stool)	40	
		4DPC						9	A		9				G - Ocular Discharge Mucoid	H - Nasal Discharge Serous	I - Nasal Discharge Mucoid	J - Diamhea Mi	K - Diarrhea Se	L - Bloody Urine	M - Icterus
		3DPC						G				g							derate		
		20PC					9				9	AD					hing	D - Depression/Lethargy	E1 - Conjunctivitis Mild/Moderate	E2 - Conjunctivitis Severe	F- Ocular Discharge Serous
		1DPC		A	A	٥	٥					٧			etance	90	C-Labored Breathing	ession/	unctivit	unctivit	r Discha
		ODPC				g			g		ŋ	G			A-inappetance	B-Vomiting	Labore	O-Depr	1-Con	2-Conj	- Ocula
		Dog	12	13	14	15	16	17	18	19	20	71	22				_				_

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		100PC   110PC   120PC   130PC   140PC   150PC   170PC   130PC   190PC   200PC   210PC		р	9 0	D,G	A A,G	d	d	9 9 9		d	6 G,1 A,G G	G,K	DPC = Day post-challenge						
enge		11DPC 12			A,D,N1	9					Р		ŋ	G,K							
t Challe		10DPC	a.		1								A,K	A,K							
erved Pos		9DPC			0	A,D							A,D,G,K,L	A,D,G,K,L						bserved	
Signs Obs	Controls	8DPC			A	A,D,K				G,K			A,D,G,K,L	A,D,G,L,N1	3.0-103.9°F)	4.0-104.9°F)	5.0-105.9°F)			nical signs o	
ola Clinica		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		2409		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					ol)		
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	ŋ	harge Mucoid	narge Serous	arge Mucoid	J - Diarrhea Mild (loose stool)	vere (bloody stool)	au	
		4DPC	A,D,K,M,N4	A,D,G,J	9	9	A	A,G,L	A,B,D,G,L		8,D,K,L	1'9	A,G		G - Ocular Discharge Mucoid	H - Nasal Discharge Serous	I - Nasal Discharge Mucoid	J - Diarrhea Mi	K - Diarrhea Severe (b)	L - Bloody Urine	M - Icterus
		3DPC			8	D,G,N1	A	A	J,K		G,K	9	A,G,N1	A,G,N2							
		2DPC		D,G,N3	N2	D,G,N1	NI	GN2	D,N2	N2	N2	N1	G,N2	A,N1			Bu	ethargy	E1 - Conjunctivitis Mild/Moderate	Severe	F- Ocular Discharge Serous
		1DPC				A,G		A		9			9		etance	9	C-Labored Breathing	D - Depression/Lethargy	unctivitis	E2 - Conjunctivitis Severe	Dischar
		ODDC									Н		9		A-inappetance	<b>B-Vomiting</b>	C-Labore	D - Depr	E1-Conj	E2-Conj	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
_		10DPC	19.3	89.8	16.9	8.5	11.3	89.8	9.1	7	7	11.7	7.7
Challenge		9DPC	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	8.6	9.3	6.4	10.5	20.7	8.3
od Cell Co	inates	7DPC	20.7	12.5	17.4	13.1	9.4	12.5	6.7	7.5	9.2	13.4	7.3
White Blo	SC Vaccinates	6DPC	20	80	13.6	12.2	10.2	13.2	11.7	7.2	6	13.9	11
canicola 1		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	4.8	7.6	14.6	9.5
Ľ		3DPC	17	9.6	12.9	12.7	2.6	11.8	10.1	9.1	9.1	15.1	12.1
		2DPC	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  $k/\mu L$ .

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		45												
		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
		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
9		10DPC			9.98	16.6	11.3			11.4			20.5	15.3
Challeng		9DPC			28.1	13.8	7.9			8.7			22.8	17.3
ount Post		3408			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	3409		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	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
7		3DPC	7.4	6.1	8.3	5.6	4.1	3.9	4.2	3.2	4	5.3	2.6	3.4
		20PC	14.2	16.7	13	9.6	5.5	6.4	7.8	9.5	6.4	11.5	6.1	10.1
		10PC	21.7	20	11.3	7.9	8.9	18.4	19.4	11.9	10.6	12.2	17.5	9.6
		Baseline (Avg2DPC, -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  $k/\mu L$ .

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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	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	265	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	٥	O	717	588	435	O	O	551	O	O	714	564		
		13DPC	O	Q	810	290	428	O	O	965	Q	O	726	475		
		120PC	O	Q	738	599	528	D	D	632	O	O	701	479		
		11DPC	D	D	823	648	552	D	D	504	D	D	744	383		
		10DPC	O	O	714	721	492	D	D	697	D	D	417	310		
llenge		9DPC	O	D	710	441	455	D	D	518	D	D	235	273		
s Post Cha		8DPC	O	D	497	302	405	D	D	412	D	D	87.1	142		
let Count	Controls	7DPC	O	207	285	ND	157	D	D	242	D	D	11.4	82.8		
ola Plate	Con	60PC	Q	123	150	194	100	11.3	42.2	122	O	44.1	2.4	6.8		
Leptospira canicola Platelet Counts Post Challenge		SDPC	O	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	eptospira was not isolated in any of the vaccinates receiving accine by SC route.												
		eptospira was not isolated in any of the vaccinates receiving accine by SC route.												ng
	vaccine	e by	SC	rou	ie.									
	Lentos	Leptospira was isolated from blood collected from dogs in the												
		Leptospira was isolated from blood collected from dogs in the control group after challenge, as shown in the following table												
	for Day	_	-				-						8	
	Dog	0	3	4	5	6	7	8	9	10	11	12	13	14
	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 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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		21DPC															
		200PC			ш		ш										
		100PC 110PC 120PC 130PC 140PC 150PC 160PC 170PC 180PC 190PC 200PC 210PC				w		ď				П					
		18DPC			٥	٥				٥							
		17DPC			w												
		16DPC										ш					
		15DPC															
		14DPC															
		13DPC			w							ш					
		12DPC					۵					Ц					
enge		11DPC										٥					
S		100PC										Ц					
rved Post		9DPC														perved	
Signs Obse	SC Vaccinates	SDPC				u.	u						ine	3.0°F		Blank - no clinical Sign observed	
ero Clinical	SC	7090											K - Bloody Urine	L-Fever >103.0°F	M - Death	Blank - no cl	
Leptospira Ictero Cinical Signs Observed Post Challenge		9090	A			ш					E	0				(loot)	()(
ন		SDPC			٥							٥	harge Serous	G - Nasal Discharge Mucoid	H- Diarrhea Mild (loose stool)	oderate (Watery stool)	J - Diarrhea Severe (bloody stool)
		4DPC											F - Nasal Discharge Serous	G - Nasal Disc	H-Diarrhea M	I- Diarrhea Moderate (	J - Diarrhea Se
		30PC			u	w						٥					o
		20PC										٥			thargy	ge Serou	ge Muco
		1DPC					ĄĒ					П	ance	130	Sion/Le	Dischar	Dischar
		00PC											A-inappetance	B-Vomiting	C - Depression/Lethargy	D- Ocular Discharge Serous	E - Ocular Discharge Mucoid
		D0g	11	12	13	7	12	16	17	18	91	8					

DPC = Day post-challenge

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		100PC 110PC 120PC 130PC 140PC 150PC 150PC 170PC 180PC 190PC 200PC 210PC		3	3 3 3						0		E 0	80					
		4DPC 15D							0					H					
		13DPC 1																	
		12DPC			ш				п										
enge		11DPC								×		×	ш						
t Chall		10DPC																	
rved Pos		9DPC		8														served	
Signs Obse	Controls	8DPC							A						ne	.0°F		Blank - no clinical Sign observed	
ro Clinical		JOPC							ſ						K - Bloody Urine	L-Fever >103.0°F	M · Death	Blank - no cl	
Leptospira Ictero Clinical Signs Observed Post Challenge		ODPC	A										A	3				(loot)	()0
ョ		SDPC							ш		0				arge Serous	arge Mucoid	H- Diarrhea Mild (loose stool)	I- Diarrhea Moderate (Watery stool)	J - Diarrhea Severe (bloody stool)
		4DPC	ь.	Ь					0	A,C,D,J		A,E			F - Nasal Discharge Serous	G - Nasal Discharge Mucoid	H- Diarrhea Mi	I- Diarrhea Mo	J - Diarrhea Se
		3DPC			_	1			0	K		L,D	E						Р
		2DPC			_	1			_	L,E	7		_				thargy	ge Serou	ge Muco
		10PC												П	tance	500	ssion/Le	Dischar	Dischar
		ODPC												П	A-inappetance	<b>B-Vomiting</b>	C - Depression/Lethargy	D- Ocular Discharge Serous	E - Ocular Discharge Mucoid
		Dog	21	22	33	24	25	36	27	38	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	89.89	8.1
		120PC	9.6	6	7.8	10	11.1	10	10.2	6.5	7	7.6
		11DPC	9.7	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
hallenge		9DPC	8.5	8.6	8.3	80	7.5	7.7	7.6	80	8.2	8.7
unt Post C		SDPC	6.4	11.1	9.6	11.8	60	10.1	11.4	7.4	7.5	9.1
d 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	6DPC	6.4	15.2	89.09	9.3	11.2	9.4	10.5	7.1	6.7	14.4
Leptospira ictero White Blood Cell Count Post Challenge		SDPC	10.1	12.4	14.2	11.3	8.3	9.1	7.2	7.3	8.7	14.8
eptospira		4DPC	6.8	9.1	9.1	12.6	80	8.1	7.5	9.9	11.7	11.9
_		3DPC	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	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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allenge		9DPC 10DPC 12DPC 13DPC 14DPC	8.1 10.4 6.4 8.5 6.5 6.2	8.2 13.4 10.1 7.7 7.6 9.4	7.1 11.9 7 9.6 11 11.8	13.7 19.2 24.9 13.3 24.4 12.3	10 13.9 9.4 8.3 9 7.1	9 10.2 13.3 8.6 8.9 10.5	12.1 8.6 8.3 11.4 7.4 9.5	11.6 11.7 14 8.3 7.8 7.7	0	8 10.3 10.1 9.9 9.4 9.6	O	9.6 14.1 9.9 10 10.1 9.3	
Cell Count Pos	5	7DPC 8DPC	6.7 6.5	9.4 7.2	7 6.5	19.8 16	12.8 9.6	11.3	7.5 8.6	14.7 10		6.2 9.9		13.5 14.5	
Leptospira ictero White Blood Cell Count Post Challenge	Controls	6DPC 7	9.6	13.4	10	16.7	10.9	15.4	9.8	8.8		7.8		10.6	
a ictero V		SDPC	6.2	7.3	6	15.3	7	12.2	10.7	7.3		7.5		12.6	
Leptospir		4DPC	8.2	6.5	7.1	11.8	9.1	11.8	14.6	7.3	26.4	7.8	19	10.7	
		3DPC	6.7	8.2	11.6	7.8	6.9	3.9	15.8	4.5	4.1	7.2	4.2	5	
		2DPC	9.6	9.3	9.4	10.6	8.5	6	9.4	6.7	5.8	5	8.3	6.2	
		1DPC	9.9	8.5	12.2	19.6	13.9	9.8	7.5	8.8	6.7	9.2	8.1	9.3	
		Baseline (Avg -2DPC, -1DPC, 0DPC)	7.4	7.4	9.3	13.7	10	8.4	7.8	7.8	7.8	8.8	11	8.3	
		000	21	22	23	24	25	26	27	28	29	30	31	32	0-000

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

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		Ų											1
		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	206	
		1DPC	432	475	595	258	380	264	407	482	467	412	
		Baseline (Avg2DPC, -1DPC, 0DPC)	449.7	518.3	489.3	451.7	357.7	369	473.7	206	477	502.3	
		Dog	11	12	13	14	15	16	17	18	19	20	

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

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				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	905	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	pon	non	a											
Study Purpose	To den	nonst	trat	e ef	fect	iven	iess	aga	inst	Lep	otos	pira	poi	non	a in	6
	week o															
<b>Product Administration</b>	Two do											<u> </u>				apart.
Study Animals	Twenty		/							_		-	_			
	Leptos									_	-	of c	ne g	grou	p of	f 10
	SC vac												11		•	
Challenge Description	Twenty		,		•								all a	nım	als	were
	challen												1		\1	1
Interval observed after	Dogs v					•			•				_			1
challenge	sample							_								
Results	Efficac	•								-	orro	cnei	emi	a in		
	vaccina	nes v	WIIE	en c	omp	are	a to	COL	uroi	S.						
	Leptos	nira	wa	e no	t isc	late	d fr	om	hlo	ad i	กลท	V O	fthe	Va(	cin	ates
		-							UIU	ou n	ıı aıı	y O.	ı tiic	vac	CIII	ates
	1000171	receiving vaccine by SC route.  Leptospira was isolated from blood collected from dogs in the														
	Leptospira was isolated from blood collected from dogs in the															
		Leptospira was isolated from blood collected from dogs in the control group after challenge, as shown in the following table														
	for Day														,	
	Dog	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
	1			+	+	+	+									
	2															
	3			+	+	+										
	4				+	+										
	5			+	+	+	+									
	6			+	+											
	7		+	+	+											
	8			+	+	+										
	9		+	+	+	+										
	10		+		+	+										
	+ is Pos	itive f	or L	epto	spira	a										
USDA Approval Date	January	y 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 Distempe	er Virus (CDV)	)	
Study Purpose	To demonstrate	effectiveness a	gainst CDV	
<b>Product Administration</b>	Two doses were	administered s	ubcutaneously 21 o	days apart
Study Animals			pies seronegative f	
	were randomly sone group of 6 c		oup of 11 SC vacci	nates and
Challenge Description	21 days after sec CDV.	ond vaccinatio	n all dogs were cha	allenged with
Interval observed after	Dogs were obser	ved for 42 day	s after challenge fo	or clinical signs
challenge	of CDV.			
Results	The study was sa (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%)	
	See the next pag	e for data.		
<b>USDA Approval Date</b>	April 6, 1998			

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2,8,10,12 2,8,10,12 20 10,12 10DPC 2 2 1,8,10,11,12 Intermittent minor stool abnormalities observed were not 31-42DPC 2,10,12 2,10,12 90PC 20 2 2222 2 Egh considered clinical signs of CDV infection. 8,10,12,14,16,17,18, 8,10,11,14 1,2,8,10,12 30DPC 10,11 8DPC 2 CDV Clinical Signs Observed Post Challenge - Control Dogs 10,12,16,17,Euth 28-29DPC 11,12 14 10,12 7DPC 2222 20 1,2,10,12 2,10,12 12 10,12 27DPC 2,12 6DPC 18 - neuromuscular Tics 20 - death Blank - No Clinical signs observed 16DPC-26DPC 2,10,12 16 - Excessive Salivation 17 - Chewing gum fits 10 2,10,12 10,12 2,10,12 SDPC 8 8 8 8 20 14 - Vomiting 10,11,12 15DPC 11,12 4DPC 2,12 2 8888 1,8,9,10,12 10,12,18 2,10,12 2,10,12 2,10,12 14DPC 3DPC 22 2 29 2- Mild/Mod. Ocular Discharge Mucoid 10,12,18 20 20 8,10,11 13DPC 2DPC 2,11 Depression/Lethargy 1,2,8,12 12DPC 1,8,10 1DPC 2 2 10-Mucous stool 11-watery Stool 8 - Dehydration 12-Bloody stool 1,2,8,10,12 8,10,12,14 8,10,12 11DPC ODPC 22 2 DG B 000

DPC – Days Post Challenge

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		21DPC	10,12									12							
		20DPC									12	12		pava					
		19DPC			10							11,12	10,12	es obse	CDV				
		18DPC										11,12 11,12		ormaliti	signs of				
		17DPC		14								10,12	10,12	ol abno	linical				
ogs		16DPC												inor sto	dered				
CDV Clinical Signs Observed Post Challenge - Vaccinated Dogs		10DPC   11DPC   12DPC   13DPC   14DPC   15DPC   16DPC   17DPC   18DPC   19DPC   20DPC												Intermittent minor stool abnormalities observed	were not considered clinical signs of CDV	'n.			
ccina		14DPC												Intermi	were n	infection.			
e - Va		13DPC																	
alleng	es	12DPC																	D
ost Ch	SC Vaccinates	11DPC																	Blank - No Clinical signs observed
ved P	SCV	10DPC													vation	fits	rTics		signs
Obser		0DPC 1DPC 2DPC 3DPC 4DPC 5DPC 6DPC 7DPC 8DPC 9DPC												99	16 - Excessive Salivation	17 - Chewing gum fits	18 - neuromuscular Tics		Clinica
igns		8DPC		L									Ц	14 - Vomiting	xcessi	hewir	neuron	20 - death	k - No
ical S		7DPC											Ц	14-	16 - 8	17.0	18-	20-02	Blan
Clini		6DPC											Ц		pic				
9		SDPC													Muc				
		4DPC						10							charge				
		3DPC												hargy	sr Dis				
		2DPC	П								Г		П	on/Let	Ocula	uoi	tool	loo	100
		1DPC	Г											oressi	J/Mod	ydrat	s snoo	tery St	ody st
		ODPC												1 - Depression/Lethargy	2- Mild/Mod. Ocular Discharge Mucoid	8 - Dehydration	10-Mucous stool	11-watery Stool	12-Bloody stool
		Dog	18	19	20	21	22	23	24	25	26	27	28						

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22DPC 23DPC 24DPC 25DPC 26DPC 27  11  10  10  10,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13  11,13	Clinical Signs Observed Post Challenge - Vaccinated Dogs	/DPC   28DPC   29DPC   30DPC   31DPC   32DPC   33DPC   34DPC   35DPC   36DPC   37DPC   39DPC   40DPC   41DPC			14	10 10 12		10 10 10	10,11,12 12	10,12 12 12 12 12 12 12	14 - Vomiting	16 - Excessive Salivation were not considered clinical signs of CDV	17 - Chewing gum fits	18 - neuromuscular Tics	4
22DPC 23DPC 24DPC 25DPC  11  10  10  11,12  11,12  11,12  11,12  11,12  11,12  11,12  11,12  10,12  11,12  10,12  11,12  10,12  11,13  10,12  10,12  11,14  10,12  10,12  10,12  11,14  10,15  10,12  10,12  10,12  10,12  10,12  10,12  10,12  10,12  10,12  10,12  10,12  10,12  10,12  10,12  10,12  10,12  10,12  10,12  10,12  10,12  10,12  10,12  10,12  10,12  10,12  10,12  10,12  10,12  10,12  10,12	CDV	27							-			Mucoid			
11 10,12 10,12 10,12 11,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,12 10,		25DPC			10,12						A50	ischarge			
10 10 11,12 11,12 10 10,12 10-Mudvation 10-Mucous sto		24DPC							10,12	10,12	/Lethan	Ocular D		lo	
11 10 10 10 10 10 10 10 10 10 10 10 10 1		23DPC								10,12	ession	Mod. 0	dration	ous sto	
		22DPC	11			10			11,12	11	1 - Depr	2- Mild/	8 - Dehy	10-Mucc	

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:  Vaccinates: 0/17 (0%)  Controls: 2/4 (50%)  See the next page for data.
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		0												
	9DРС							9DPC										O							
rols	8DPC		C					8DPC																	
ated Cont	лорс		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	G,H			SDPC											٥						
	4DPC			I				4DPC																	
	3DPC							3DPC																	
	2DPC							2DPC													O				
	1DPC	۵						1DPC											٥						
	0DPC							0DPC			D														
	D <sub>0</sub>	1	2	ო	4			Dog	1	2	က	4	S	9	7	00	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
ontrols	SDPC	101.3	101.0	eN	Na
Non-Vaccinated Controls	7DPC	101.3	101.0	Na	Na
Von-Vac	6DPC	100.7	99.3	100.0	93.4
_	SDPC	101.9	102.6	101.3	101.7
	4DPC	102.1	103.0	104.5	104.1
	3DPC	101.1	100.9	101.3	101.2
	2DPC	101.3	101.7	102.5	101.4
	1DPC	101.3	101.2	101.6	101.2
	0DPC	100.4	99.7	101.2	100.4
	Cat ID	1	2	33	4

	14DPC	101.8	102.1	100.8	102.3	101.8	102.0	101.6	101.2	102.1	101.6	102.2	101.9	101.3	101.7	102.3	102.3	101.7	
	13DPC	101.3	101.3	101.4	100.9	101.3	102.7	101.1	101.3	101.8	101.0	102.1	101.8	101.1	100.5	101.7	101.8	101.2	
	12DPC	101.7	101.7	101.3	101.2	101.5	102.5	101.3	101.0	101.4	101.1	101.9	101.4	101.2	101.0	101.3	101.4	101.4	
	11DPC	101.8	101.7	101.0	101.4	101.7	102.4	101.0	101.3	102.3	101.2	102.5	101.6	101.1	100.8	101.4	101.3	101.2	
	10DPC	101.1	101.4	100.9	101.3	101.6	102.3	101.2	101.1	101.7	101.1	101.7	101.3	101.1	101.4	101.2	101.7	101.6	
	9DPC	101.7	101.6	101.2	101.4	101.5	101.8	101.0	101.1	101.3	101.1	102.3	101.2	101.3	100.4	101.8	101.9	101.4	
	SDPC	101.5	101.7	101.4	101.7	101.3	101.5	101.3	101.1	101.5	101.1	102.3	101.0	101.1	100.7	101.4	101.6	101.7	
Vaccinates	7DPC	101.0	101.3	100.5	101.3	101.1	101.4	101.2	101.0	100.9	100.9	101.5	101.5	101.7	100.7	100.7	101.3	101.3	
Ν̈́	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	allenge
	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	's Post Ch
	Cat ID	2	9	7	600	6	10	11	12	13	14	15	16	17	18	19	20	21	DPC = Days Post Challenge

DPC = Days Post Challenge

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Total White Blood Cell Counts (x1000/uL)

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

	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
	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
	SDPC	9.8	10.3	10.9	8.2	8.2	20.3	18.9	11.2	14.1	11.4	10.3	12.0	11.0	9.4	16.3	18.3	10.1
	7DPC	9.1	8.6	8.9	9.8	8.1	10.2	10.7	12.1	11.5	14.1	10.4	15.4	6.6	9.4	20.3	19.6	14.5
	6DPC	9.18	9.61	8.73	8.40	8.17	8.00	7.71	10.70	11.80	17.10	11.0	12.6	7.8	11.8	17.2	14.1	12.9
Vaccinates	SDPC	12.7	10.1	10.2	9.3	9.3	10.0	8.8	10.4	11.2	14.0	10.9	14.7	12.7	14.9	28.6	28.2	14.4
Vacci	4DPC	10.3	9.3	9.4	9.0	9.7	6.6	9.4	13.9	11.0	20.4	10.6	16.0	9.3	14.7	21.9	18.9	12.8
	3DPC	8.4	11.0	9.1	10.0	10.3	12.3	Na	15.3	15.1	Na	12.6	16.0	Na	14.6	20.0	17.4	15.9
	2DPC	11.8	12.7	9.3	10.2	12.8	15.1	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

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			CPV Titer From Fecal Material (Log FAID <sub>50</sub> /mg Feces)	r From Fe	cal Mate	erial (Log	FAID <sub>50</sub> /I	ng Feces	_		
				Nor	-Vaccina	Non-Vaccinated Controls	trols				
at ID	0DPC	1DPC	2DPC	3DPC	4DPC	SDPC	6DPC	7DPC	SDPC	9DPC	10DPC
1	<1.5	<1.5	<1.5	<1.5	2.4	4.2	5.8	5.5	5.2	2.0	1.5
2	<1.5	<1.5	<1.5	<1.5	1.5	3.8	5.6	5.4	4.5	3.5	3.4
3	<1.5	<1.5	<1.5	<1.5	3.2	5.5	NS	NS	NS	NS	NS
4	<1.5	<1.5	<1.5	<1.5	3.5	SN	6.2	NS	NS	NS	NS

				_	_		_	_		_			_			_		_
	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
<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 2 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

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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	7370
		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	44505
		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	3000
ation Titer	d Controls	41DPV1	<2	<2	<2	<2	<2		ites	41DPV1	1024	362	1024	724	45	<2	1024	<2	<2	45	<2	512	<2	<2	512	724	4	1448	1024	4440
Serum Neutrlization Titer	Non-Vaccinated Controls	28DPV1 (0DPV2)	<2	<2	<2	<2	<2	;	Vaccinates	28DPV1 (0DPV2)	<2	<2	2	<2	<2	<2	<2	<2	2	<2	2	<2	2	5	<2	<2	<2	<2	<2	Ç
		7PV1	4	3	23	10	9			7PV1	8	23	23	23	16	23	4	80	64	9	16	2	11	23	19	4	8	11	4	4
		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	
		-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	100
		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	5

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

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Lymphocyte Counts Post Challenge (x103/μl)

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	10DPC	Na	2.13	2.70	3.35	2.60		10DPC	3.14	1.67	2.10	3.12	1.98	2.77	2.33	2.38	2.76	2.72	4.83	2.59	3.30	3.28	4.78	3.26	4.33	1.22	3.54	0.92
	9DPC	Na	1.27	2.11	2.09	2.08		9DPC	2.64	3.28	2.52	2.66	1.09	2.24	1.91	2.59	2.83	3.17	4.57	2.71	3.24	2.59	3.98	2.35	3.34	1.14	2.86	3.50
	8DPC	Na	1.17	1.52	1.52	1.74		8DPC	3.01	2.92	2.42	2.87	1.36	2.32	1.67	2.51	2.64	3.24	4.18	0.93	2.27	1.34	2.26	2.28	3.23	1.44	2.68	3.61
	7DPC	0.27	1.04	1.66	2.03	2.04		7DPC	2.57	3.23	2.16	2.41	1.49	1.97	0.22	2.23	2.65	3.22	4.10	2.51	2.90	2.78	3.27	2.12	3.93	1.53	2.46	3.57
	6DPC	0.74	0.69	1.59	1.75	1.09		6DPC	3.31	3.20	2.38	2.34	1.57	2.44	1.81	2.52	2.44	3.09	3.66	3.29	3.13	3.04	3.98	1.98	2.42	1.72	2.70	2.46
	5DPC	0.28	0.58	0.70	0.67	1.00		5DPC	2.66	2.73	1.73	2.75	1.19	1.62	1.52	1.64	2.65	2.57	3.07	2.98	2.35	2.69	3.04	1.73	2.36	1.29	2.03	2.52
	4DPC	0.30	0.29	1.42	1.17	0.92		4DPC	2.39	3.03	1.65	2.03	1.26	1.79	1.68	1.52	3.01	2.39	3.28	2.85	2.83	2.93	3.05	2.50	3.75	1.45	2.03	3.56
Controls	3DPC	0.80	1.82	2.42	2.31	2.25	Vaccinates	3DPC	2.42	3.27	2.32	2.91	1.14	1.16	1.53	1.78	2.56	2.57	3.76	3.04	3.35	2.62	2.62	2.39	3.38	1.47	2.67	3.56
ŏ	2DPC	1.45	2.36	2.26	1.92	2.37	Vac	2DPC	2.25	3.05	2.46	2.45	1.32	1.55	1.51	1.93	2.43	1.88	3.62	2.81	2.08	2.84	2.48	2.22	3.18	1.35	2.24	2.89
	1DPC	1.71	2.28	2.32	2.68	2.29		1DPC	2.05	3.32	2.42	3.23	1.23	1.84	1.18	1.81	1.93	2.43	3.57	3.10	2.56	2.42	2.97	2.58	3.96	1.63	2.09	2.68
	Average	1.27	2.30	1.86	2.13	2.41		Average	2.95	2.43	2.28	1.72	0.91	1.67	1.21	1.99	2.94	1.92	2.48	2.39	2.09	2.17	2.46	2.00	3.40	1.27	1.78	2.42
	0DPC	1.38	2.07	1.87	2.52	2.30		0DPC	2.74	2.34	2.34	2.46	1.16	1.73	1.18	2.00	3.27	2.24	3.02	2.66	2.06	2.11	2.50	2.05	3.35	1.51	2.32	2.15
	-1DPC	1.20	2.59	2.14	2.19	2.26		-1DPC	3.06	2.50	2.40	1.59	96.0	1.84	1.22	1.89	2.80	2.25	2.24	2.30	2.54	2.14	2.82	2.11	3.05	1.46	2.04	2.68
	-2DPC	1.24	2.24	1.57	1.67	2.68		-2DPC	3.05	2.45	2.09	1.10	0.62	1.43	1.23	2.07	2.74	1.26	2.17	2.21	1.68	2.25	2.06	1.83	3.80	0.84	0.97	2.43
	CatID	6	11	19	21	27		CatID	1	2	3	4	9	9	7	8	10	13	14	15	16	17	18	20	22	23	24	28

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10DPC 101.9 101.4 101.9 10DPC 102.6 101.9 102.1 101.9 101.6 102.1 102.0 101.9 101.9 101.6 102.2 101.7 102.1 102.7 102.1 102.7 101.7 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 12 101.6 100.9 102.9 101.7 102.8 102.4 102.0 101.9 101.5 102.0 101.9 101.6 SDPC Na 101.3 SDPC 102.1 102.8 102.2 101.8 101.3 102.1 102.1 100.9 102.2 102.4 101.8 101.9 103.0 103.1 102.5 102.7 103.0 102.4 102.4 101.9 101.9 102.0 101.9 102.8 102.0 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 102.8 102.3 102.0 103.0 103.4 102.8 102.4 102.1 102.0 102.0 101.8 102.0 103.2 6DPC 101.5 103.1 102.7 Non-Vaccinated Controls SDPC 104.6 103.4 103.8 103.4 102.8 102.0 102.7 102.1 102.6 102.4 103.1 102.5 102.5 102.6 102.4 102.1 102.1 102.6 101.8 102.5 102.4 102.2 SDPC Vaccinates 4DPC 101.9 4DPC 101.7 102.7 102.4 103.5 102.4 103.0 102.6 103.0 103.2 102.7 102.8 102.5 102.7 102.3 102.2 102.8 103.2 102.2 103.2 103.1 102.6 102.3 101.4 102.7 103.3 102.4 102.8 102.0 101.9 102.6 101.5 102.0 101.8 102.9 101.9 102.1 103.3 102.8 102.2 102.4 102.4 3DPC 3DPC 102.2 102.7 102.5 102.5 102.3 102.0 102.6 102.1 101.3 102.1 102.8 102.1 102.1 101.9 102.4 102.7 102.6 101.9 102.5 102.3 103.2 101.7 102.8 102.4 102.3 2DPC 2DPC 102.9 102.8 102.3 103.0 103.4 102.5 102.5 101.9 102.9 102.0 102.5 102.5 102.8 102.0 103.3 102.8 1DPC 1DPC 102.4 102.7 102.1 102.1 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 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> <u> 15</u> <u> 15</u> <u> 15</u> s 5 <u> 15</u> 1.5 s 1.5 s 1.5 <u> 5</u> 4.5 ğ 4 8DPC 8DPC s 1.5 ≥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> 51.5 4.2 7DPC 7DPC s1.5 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 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 9.7 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 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 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 s1.5 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 s 1.5 s 1.5 s 1.5 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 ODPC 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. s 1.5 CatID CatID 19 10 13 14 15 16 22 22 23 23 Ξ 21 27 17 24 6 က 4 5 9  $\infty$ 2

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Positive For CPV >1.5 log10 FAID30/mL

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 >	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	

<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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