

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

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	47N9.20
True Name	Canine Distemper-Adenovirus Type 2-Parvovirus Vaccine, Modified Live Virus, Leptospira Canicola-Grippotyphosa- Icterohaemorrhagiae-Pomona Bacterial Extract
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	ULTRA Duramune DAP + 4L - Elanco US Inc.
Date of Compilation Summary	December 19, 2019

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

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Study Type	Efficacy			
Pertaining to	Infectious Canir	ne Hepatitis Vir	us	
Study Purpose	To demonstrate (ICH)	effectiveness ag	gainst Infectious C	anine Hepatitis
<b>Product Administration</b>		administered s	ubcutaneously (SC	c) 21 days apart
Study Animals			pies, seronegative	
	randomly sorted	into one group	of 11 SC vaccinat	es and one
	group of 6 contr			
Challenge Description	21 days after sec	cond vaccination	n all dogs were cha	allenged with
	Infectious Canir			
Interval observed after	Puppies were ob	served for 21 d	ays after challenge	e for clinical
challenge	signs.			
Results		atisfactory per t	the criteria in 9 CF	R 113.305
	(1)(ii)(A)(B)			
	_		1	1
		Mortality	Clinical Signs of	
		ivioreality	CDV Infection	
	SC Vaccinates	0/11 (0%)	0/11 (0%)	
	Controls	6/6 (100%)	6/6 (100%)	
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				Car	nine Infe	ectious He	patitis Clinical Sigr	ıs Obs	serve	d Pos	t Cha	lleng	e					
Dog	Treatment	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC	15DPC	16DP
1	Control					22	N/A				•		•			•		
2	Control					1,4,7,20	1,3,5,6,15,17,20,22***											
3	Control				3,13,23**	1,3,23,22***	N/A						NA					
4	Control				23**	1,3,7	1,3,6,7,17,20,22***	1										
5	Control			23*	3	22	N/A	1										
6	Control			7	7	22	N/A	1										
19	SC Vac																	
20	SC Vac																	
21	SC Vac																	
22	SC Vac															6		
23	SC Vac																	
24	SC Vac										6							
25	SC Vac																	
26	SC Vac																	
27	SC Vac																	
28	SC Vac																	
29	SC Vac								6							6		
	1 - Depression	on/Let	nargy			6 - Serous o	cular discharge		15 - Ex	cessive	Saliva	tion		23 - O	ther			
	3- Dehydrati	ion				7 - Mild/Mo	derate mucopurulent		17 - Ic	teric Gu	ıms			* Icter	ic Luml	oar onl	У	
	4 - Mild/Mo	derate	Conju	nctivitis		Ocular Disch	arge		20 - Pe	etechia	Pain /			** Icte	ric lum	bar an	d ears	
	5 - Severe Co	onjunc	tivitis			13 - Vomitin	g		Ecchyı	notic				***- n	noribun	d and	euthani	zation
				NO Clinic	al signs ob	served in any	group after 16DPC		22 - D	eath				DPC – [	Days po	st chall	enge	

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Study Type	Efficacy
Pertaining to	Canine Adenovirus Type II
Study Purpose	To demonstrate effectiveness against Canine Adenovirus Type II (CAV2)
<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	Puppies were observed for 21 days after challenge for clinical
challenge	signs.
Results	The study was considered satisfactory by the reduction in clinical signs and virus shedding in the vaccinates when compared to the control animals.  Raw Data:  Data tables are appended to the end of this summary
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	10DPC 11DPd12DPd13DPd14DPd15DPd16DPd17DPd18DPd19DPd21DPd						1 1	1,2	1 1 1											1 1 1 1				7-Inappetance	Blank - No Clinical signs observed
9	C13DPC14D							1,2 1	1											1				7-11	BIS
CAV2 Clinical Signs Observed Post Challenge	11DPC12DP	L						1	1		1									1					6 - depression/lethargy
od Pos	10DPC			1				2,4	1			1								1				hing	ression
bserve	9DPC	2	2	1	2	1	1	1	1	4	1,2	1									1,2			5 -Retching	6 - dep
gns O	8DPC	2	1,2	1	1,2,	1		1	1	4	1	1			1					1	1				
inical S	7DPC		1,2	1	1,2,4	1,4		1,2,4,5,6	1	1	1	1,2							1	1	1				
AV2 C	6DPC	1,2	1,2	1,2	1,2	1	4	1,2,4	1,6	1	1	1,2						1	1	1	1			Sneezing	- Coughing
J	SDPC	1	1	1	1,2	1		1	1,2		1				1					1	1				4 - Cou
	4DPC	L					2		1		1	2								1					
	3DPC	L							1,2				L											98	e .
	0DPC 1DPC 2DPC 3DPC 4DPC	L							1,2											1				1 - Ocular Discharge	2- Nasal Discharge
	1DPC	L							1											1				cular C	O lesi
	ODPC	L																						1-0	2- Na
	Group	Control	Control	Control	Control	Control	SC	SC	SC	SC															
	Dog	1	2	3	4	2	9	7	80	6	10	11	23	24	25	26	27	28	29	30	31	32	33		

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						8	V2 Isc	platio	n fron	n Nass	al Swa	ab San	nples	(TCIDs	CAV2 Isolation from Nasal Swab Samples (TCID <sub>50</sub> /100uL)	<u>1</u>						
Dog	Group	ODPC	1DPC	2DPC	3DPC	4DPC	SDPC	6DPC	7DPC 8DPC	-	9DPC 1	10DPC 1	1DPC 1	2DPC 1	9DPC  10DPC  11DPC  12DPC  13DPC  14DPC  15DPC	3PC 15D	PC 16D	C 17DP	C 18DPC	19DPC	16DPC 17DPC 18DPC 19DPC 20DPC 21DPC	21DPC
1	$\vdash$				2	2.5	3.63	3.5	51.83		Г	H	H	H	H	Н	H	L				
2	Control				2	2.83	3.5	3.83	2.17							51.	.83					
m	Control				51.63	3.5	4.17	3.38							2	2.17						
4	Control					2.63	3.38	4.31	2.35			-1	51.63									51.63
2	Control				2.38	5.6	4.38	3.6	\$2.63													
9	Control				51.83	\$1.83	4.5	3.63	3.63													
7	Control				\$1.63	2.75	4.5	4.5	≤1.83													
00	Control				2.38	2.83	3.63	3.17														
6	Control				51.63	2.83	2.83	4.38												51.83		
10	Control				\$1.63	2.17	3.63	3.5				-1	51.63	2.38	2.5 51	51.83						
11	Control				51.83	2.5	4.5	4.38					VI	51.63	51.83 51	51.63 51.63	63	51.63		\$1.63		
23	SC														_		_					
24	SC		51.6				2.38															
25	SC					\$1.63																
26	SC								2.63													\$1.63
27	SC		≤1.63											VI	51.63							
28	SC										7.	51.63										
29	SC				2	£1.83								VI	51.63	≤1.63	63					
30	SC																					
31	SC													VI	51.63							
32	SC		51.6			<b>&lt;1.83</b>	2.63	2.5														
33	SC															<1.63	63					
Blank	Blank - No CAV2 titer detected	titer de	tected																			
PPC-	DPC - Days Post Challenge	Challen	90																			

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Study Type	Efficacy
Pertaining to	Leptospira canicola
Study Purpose	To demonstrate effectiveness against <i>Leptospira canicola</i> in 6
	week old dogs.
Product Administration	Two doses were administered subcutaneously (SC) 3 weeks
	apart.
Study Animals	Twenty-three (23) 6 week old puppies serologically negative for
	Leptospira were randomized into one group of 11 SC vaccinates
	and one group of 12 controls.
Challenge Description	Twenty-one (21) days after second vaccination all animals were
	challenged with <i>Leptospira canicola</i> organisms.
Interval observed after	Dogs were observed daily for 21 days after challenge for clinical
challenge	signs associated with <i>L. canicola</i> . Blood samples were collected
	through 14 days after challenge.
Results	Efficacy was determined by comparing vaccinates versus
	controls in clinical signs, thrombocytopenia, and leukopenia.
	A dog was considered to have thrombocytopenia if the platelet
	count dropped below 200 k/µL and the count was less than 50%
	of the baseline value.
	of the suseime value.
	A dog was considered to have leukopenia if the platelet count
	dropped below 6 $k/\mu L$ and the count was less than 50% of the
	baseline value.
	Data tables are appended to the end of this summary.
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		21DPC																			
		10DPC   11DPC   12DPC   13DPC   14DPC   15DPC   16DPC   17DPC   18DPC   19DPC   21DPC		9	B)																
		19DPC			8									Ī	<u>و</u>						
		18DPC				9									alleng	,					
		17DPC							AG						st-ch						
		16DPC				9							Ξ		DPC = Day post-challenge	,					
		15DPC			А	AG			А						C = D						
		14DPC							A						DP.						
		13DPC																			
		12DPC																			
llenge		11DPC																			
st Cha		10DPC				A															
erved Po		9DPC									g									perved	
Signs Obs	SC Vaccinates	8DPC													3.0-103.9°F)	4.0-104.9°F)	5.0-105.9°F)			nical signs ol	
ola Clinical	SCV	7DPC									9				N1 - Fever (103.0-103.9°F)	N2 - Fever (104.0-104.9°F)	N3 - Fever (105.0-105.9°F)	N4 - <99.6°F	P - Death	Blank - no clinical signs observed	
Leptospira canicola Clinical Signs Observed Post Challenge		6DPC				9						А									
Lept		SDPC									9	9			harge Mucoid	harge Serous	arge Mucoid	J - Diarrhea Mild (loose stool)	K - Diarrhea Severe (bloody stool)	a.	
		4DPC						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						9				G									
		2DPC					9				G	AD					ing	ethargy	E1 - Conjunctivitis Mild/Moderate	Severe	F- Ocular Discharge Serous
		1DPC		А	A	٥	0					А			tance	20	d Breath	ssion/L	ınctivitis	ınctivitis	Dischan
		0DPC				9			9		g	g			A-inappetance	<b>B-Vomiting</b>	C-Labored Breathing	D - Depression/Lethargy	E1 - Conju	E2 - Conjunctivitis Severe	F- Ocular
		Dog	12	13	14	15	16	17	18	19	20	21	22								

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		PC 21DPC																				
		100PC   110PC   120PC   130PC   140PC   150PC   160PC   170PC   180PC   190PC   210PC				8	A,G						A,G G			DPC = Day post-challenge						
		VC 15DPC 16DP					А			9 9			1′9			C = Day p						
		3DPC 14DF		Ь	9			Ь	۵			Ь			[	DI	_					
		12DPC 1			٥	9′0				9	Ь		9	G,K								
allenge		C 11DPC	Ь		A,D,N1	9							9	G,K								
ost Cha													A,K	A,K								
served P		9DPC			Q	A,D							A,D,G,K,L	A,D,G,K,L							pserved	
Signs Ob	Controls	8DPC			A	A,D,K				G,K			A,D,G,K,L	A,D,G,L,N1		3.0-103.9°F)	1.0-104.9°F)	5.0-105.9°F)			ical signs o	
ola Clinical	)	7DPC		C,D,G,L,N4	A,G	A,G,K	A,D,G			9			A,D,G,K,L	A,D,K,L,N1		N1 - Fever (103.0-103.9°F)	N2 - Fever (104.0-104.9°F)	N3 - Fever (105.0-105.9°F)	N4 - <99.6°F	P - Death	Blank - no clinical signs observed	
Leptospira canicola Clinical Signs Observed Post Challenge		6DPC		A,D,K	A,K	A,D,J	A,K	A,D,E2,M,N4	A,D,E1,K,L,M,N4	A,D,G,K		A,D,G,K,L,M,N4	A,D,G,K,L	A,D,G,K,L								
Lep		SDPC		A,D,G		Q	A,N1	A,D,G,K,L,M,N4	D,G,K,L,N4	S,K	D,G,K,L,N4	D,K,L	A,B,J	9		harge Mucoid	narge Serous	arge Mucoid	J - Diarrhea Mild (loose stool)	K - Diarrhea Severe (bloody stool)	a.	
		4DPC	A,D,K,M,N4	A,D,G,J	9	9	А	A,G,L	A,B,D,G,L		B,D,K,L	1′9	A,G			G - Ocular Discharge Mucoid	H - Nasal Discharge Serous	I - Nasal Discharge Mucoid	J - Diarrhea Mi	K - Diarrhea Se	L - Bloody Urine	M - Icterus
		3DPC			8	D,G,N1	А	A	J,K		G,K	9	A,G,N1	A,G,N2								
		2DPC		D,G,N3	N2	D,G,N1	N1	GN2	D,N2	N2	N2	N1	G,N2	A,N1				ji Bi	ethargy	E1 - Conjunctivitis Mild/Moderate	Severe	F- Ocular Discharge Serous
		1DPC				A,G		A		9			9			etance	20	d Breath	D - Depression/Lethargy	unctivitis	unctiviti	r Dischar
		0DPC									н		9			A-inappetance	<b>B-Vomiting</b>	C-Labored Breathing	D - Depr	E1 - Conj	E2 - Conjunctivitis Severe	F- Ocula
		Dog	23	24	25	26	27	28	29	30	31	32	33	34								

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

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

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		14DPC			21.9	13.9	13.3			12.2			16.9	20.2
		13DPC			29.4	12.7	11.5			16.7			17.4	15.9
		12DPC			26.2	11.5	15			12.69			26.3	15.7
		11DPC			36.7	9.6	13.9			9.2			31.5	10.9
4		10DPC			36.6	16.6	11.3			11.4			20.5	15.3
Challenge		90РС			28.1	13.8	7.9			8.7			22.8	17.3
Leptospira canicola White Blood Cell Count Post Challenge		8DPC			26	11.7	16.2			10.4			22.8	12.6
od Cell Co	rols	7DPC		20.5	17		21			11.1			13	12
White Blo	Controls	бррс		14.6	13.6	8	19.4	13.2	17.5	10.6		15.8	8.7	9
canicola		5DPC		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	6	6	5.3	5.6
1		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	7.9	8.9	18.4	19.4	11.9	10.6	12.2	17.5	9.6
		Baseline (Avg -2DPC, -1DPC, 0DPC)	18.3	16.1	17.1	6	10.4	9.6	12.2	9.5	8.9	11.9	11.8	7
		Dog	23	24	25	26	27	28	29	30	31	32	33	34

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

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	14DPC	470	467	640	461	390	278	572	524	469	583	593
	13DPC	511	510	802	463	399	257	554	516	464	474	495
	12DPC	483	550	508	438	428	232	406	418	462	429	497
	11DPC	381	616	568	260	302	261	480	414	601	521	200
	10DPC	512	501	267	482	519	270	405	381	493	501	492
	9DРС	631	470	695	497	512	288	483	476	662	581	297
	8DPC	478	565	693	576	655	314	463	379	704	650	473
inates	7DPC	582	636	604	633	558	351	247	375	706	514	469
SC Vacc	6DPС	531	467	497	612	555	389	542	376	538	441	517
	5DPC	512	539	536	503	492	329	453	375	523	469	576
	4DPC	473	576	444	421	456	324	398	403	483	447	478
	3DPC	452	573	505	543	452	311	381	324	530	476	581
	2DPC	480	559	452	381	409	247	356	353	497	354	455
	1DPC	538	679	571	407	377	243	331	330	494	332	413
	Baseline (Avg -2DPC, -1DPC, 0DPC)	444.3	551.3	473.3	459.7	477.3	318	425.7	348.7	555.3	378.3	469.3
	Dog	12	13	14	15	16	17	18	19	20	21	22
	SC Vaccinates	Baseline (Avg - 2DPC) - 1DPC, -1DPC, 0DPC)         1DPC and a control of a co	Baseline (Avg -2DPC, -1DPC)         1DPC ODPC)         3DPC AVG	Baseline (Awg -2DPC, -1DPC, -1DPC)         1DPC (Awg -2DPC, -1DPC, -1DPC)         3DPC (AWg -2DPC, -1DPC, -1DPC, -1DPC, -1DPC)         5DPC (AWg -2DPC, -1DPC, -1DPC, -1DPC, -1DPC, -1DPC, -1DPC, -1DPC, -1DPC)         3DPC (AWg -2DPC, -1DPC, -1DP	Baseline (Avg - 2DPC)         SC Vacinates           -1DPC, -1DPC, DDPC)         1DPC         3DPC         4DPC         5DPC         7DPC         8DPC         478         478         479         1DPC         1DPC         11DPC         13DPC         13DPC	Baseline (Avg -2DPC)	Baseline (Avg - 2DPC, -1DPC)         3DPC         4DPC (AVR - 2DPC, -1DPC)         5DPC (AVR - 2DPC, -1DPC)         5DPC (AVR - 2DPC, -1DPC)         5DPC (AVR - 2DPC, -1DPC, -1DPC)         5DPC (AVR - 2DPC, -1DPC, -1DPC, -1DPC)         5DPC (AVR - 2DPC, -1DPC, -1DPC, -1DPC, -1DPC)         5DPC (AVR - 2DPC, -1DPC, -1DPC	Baseline (Avg-2DPC, 1DPC) 4.1         1DPC (Avg-2DPC, 1DPC) 4.2         1DPC (Avg-2DPC, 1DPC) 4.2         1DPC (Avg-2DPC, 1DPC, 1DPC, 1DPC, 1DPC, 1DPC) 4.2         1DPC (Avg-2DPC, 1DPC, 1DP	Baseline (Avg-2DPC, -1DPC, -1D	Baseline         Actorinates         SC Vaccinates           Avg -2DPC, -1DPC,	SC Vaccinates    Awg-2DPC,   1DPC   2DPC   3DPC   4DPC   5DPC   6DPC   7DPC   8DPC   4DPC   4	Baseline (Awg-2DPC, -1DPC)         10PC         3DPC         4DPC         4DPC <th< td=""></th<>

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

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		14DPC	D	D	717	588	435	D	D	551	D	D	714	564		
		13DPC	Q	Q	810	290	428	Q	D	965	Q	O	726	475		
		12DPC	O	a	738	599	528	O	O	632	O	O	701	479		
		11DPC	O	a	823	648	552	Q	D	504	Q	O	744	383		
		10DPC	O	a	714	721	492	a	O	269	Q	Q	417	310		
allenge		90РС	O	a	710	441	455	a	O	518	Q	O	235	273		
Leptospira canicola Platelet Counts Post Challenge		8DPC	O	a	497	302	405	Q	O	412	Q	O	87.1	142		
let Count	Controls	7DPC	O	207	285	QN	157	a	O	242	Q	Q	11.4	82.8		
cola Plate	Con	90РС	O	123	160	194	100	11.3	42.2	122	O	44.1	2.4	8.9		
spira canio		5DPC	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		
		ЗДРС	11	64.1	187	196	119	45.9	195	107	80.2	103	115	64.5		
		2DPC	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  $k/\mu L$ .

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

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## Isolation of Leptospira from Blood Collected from Dogs Post Challenge

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

NA - Animal Dead or euthanized / no sample taken

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<sup>+ -</sup> Positive for Leptospira

<sup>\*</sup>Leptospira was not isolated in any of the SC vaccinates

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

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Leptospira Ictero Clinical Signs Observed Post Challenge	SC Vaccinates	3DPC 4DPC 5DPC 6DPC 7DPC 8DPC 9DPC 10DPC 11DPC 12DPC 13DPC 13DPC 15DPC 1	Y Y		3 0 3 3 3	3 0 3	3 3	<b>A</b>					F - Nasal Discharge Serous K - Bloody Urine	G - Nasal Discharge Mucoid L - Fever >103.0°F	H- Diarrhea Mild (loose stool) M - Death	I- Diarrhea Moderate (Watery stool) Blank - no clinical Sign observed	
													F - Nasal Discharge	G - Nasal Discharge	H- Diarrhea Mild (I	I- Diarrhea Modera	I. Diarrhoa Couoro
		3DPC			В	п						Q				SL	3
		2DPC										Q			ethargy	arge Serou	
		ODPC 1DPC					A,E						A-inappetance	B-Vomiting	C - Depression/Lethargy	D- Ocular Discharge Serous	
		Dog	11	12	13	14	15	16	17	18	19	70	1				ľ

DPC = Day post-challenge

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		21DPC																	
		20DPC																	
		19DPC		ш	ш														
		18DPC			ш						O		O	8					
		17DPC			ш														
		16DPC			ш								П						
		15DPC							0										
		14DPC																	
		13DPC																	
		12DPC			ш				Б										
age e		11DPC								M		M	E						
Challe		100PC   110PC   120PC   130PC   140PC   150PC   170PC   180PC   190PC   200PC   210PC								~		V							
Post (		9DPC																_	
erved		36																bservec	
Leptospira Ictero Clinical Signs Observed Post Challenge	slo.	8DPC							A									Blank - no clinical Sign observed	
al Sign	Controls														/Urine	103.0°F	_	clinica	
Ginic		7DPC							_						K - Bloody Urine	L - Fever >103.0°F	M - Death	ank - no	
cter															ż	ن	Σ	<u>=</u>	
ospira		6DPC	A										A	ш				=	
Lept																ъ	(100	eny sto	(stool)
		SDPC							Б		0				Serous	e Mucoi	oose st	te (Wat	(plood)
															scharge	ischarg	Mild (	Modera	Severe
		4DPC	ı.	ᇤ					٥	A,C,D,J		A,E			F - Nasal Discharge Serous	G - Nasal Discharge Mucoid	H- Diarrhea Mild (loose stool)	I- Diarrhea Moderate (Watery stool)	J - Diarrhea Severe (bloody stool)
															Œ	-6	꿒	-	=
		3DPC			_	1			Q	Х		ΓΊ	3					S	ë
		2DPC			_	_			_	L,E	_		_				thargy	ge Sero	rge Muc
		1DPC												П	ance	50	ssion/Le	Dischar	Discha
		ODPC :													A-inappetance	<b>B-Vomiting</b>	C - Depression/Lethargy	D- Ocular Discharge Serous	E - Ocular Discharge Mucoid
						_		,-			_				-H	<b>&amp;</b>	ن	۵	ய்
		Dog	21	22	23	24	25	26	27	28	29	30	31	32					

DPC = Day post-challenge

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	14DPC	6.4	12.3	8.4	9.1	10.9	8.3	7.3	6.4	6.7	8.9
	13DPC	7.2	9.1	7.8	12.8	7.5	8.3	7.5	7.8	8.8	8.1
	12DPC	9.6	6	7.8	10	11.1	10	10.2	6.5	7	7.6
	11DPC	6.7	10.2	6.7	9.8	7.7	9.5	7.1	8.1	7.8	12.6
	10DPC	8.9	7.7	10.6	13.2	10.4	8.7	11.7	6	7.7	12.5
	9DPC	8.5	9.8	8.3	8	7.5	7.7	7.6	8	8.2	8.7
	8DPC	6.4	11.1	9.6	11.8	8	10.1	11.4	7.4	7.5	9.1
inates	7DPC	6.4	8.2	9.2	7.3	10.2	8.4	9.4	8.4	10.5	6.4
SC Vacc	бОРС	6.4	15.2	8.8	9.3	11.2	9.4	10.5	7.1	6.7	14.4
	5DPC	10.1	12.4	14.2	11.3	8.3	9.1	7.2	7.3	8.7	14.8
	4DPC	6.8	9.1	9.1	12.6	8	8.1	7.5	6.6	11.7	11.9
	3DPC	7.9	8.9	13.2	8.2	9	6.8	8.1	9.1	11.7	9.1
	2DPC	12.4	10.4	9.6	12.6	8.6	9.5	7.8	10.5	8.4	5.3
	1DPC	7.3	13.9	15.4	7.6	11.4	8.8	7.1	7.7	13.8.	9.9
	Baseline (Avg -2DPC, -1DPC, 0DPC)	7.2	10	7.6	13.4	9.8	9.1	9.1	7.2	9.5	13.1
	Dog	11	12	13	14	15	16	17	18	19	20
	SC Vaccinates	Baseline (Avg -2DPC, -1DPC, 0DPC)         1DPC         2DPC         4DPC         5DPC         7DPC         8DPC         9DPC         1DPC         12DPC         13DPC	Baseline (Avg -2DPC, -1DPC) 0DPC)         1DPC -1DPC, -1DPC, -1DPC         3DPC -1DPC, -1DPC, -1DPC         5DPC -1DPC, -1DPC, -1DPC, -1DPC, -1DPC         4DPC -1DPC,	Baseline (Avg -2DPC, -1DPC)         1DPC (Avg -2DPC, -1DPC)         1DPC (Avg -2DPC, -1DPC, -1DPC)         1DPC (Avg -2DPC, -1DPC, -1DPC, -1DPC, -1DPC, -1DPC)         1DPC (Avg -2DPC, -1DPC, -1DP	Baseline (Avg -2DPC) (Avg -2DPC)         3DPC (Avg -2DPC) (Avg -2DPC)         5DPC (Avg -2DPC) (Avg -2DPC)         5DPC (Avg -2DPC) (Avg	Baseline (Avg-2DPC, -1DPC)         1DPC (Avg-2DPC, -1DPC)         1DPC (Avg-2DPC, -1DPC, -1DPC)         1DPC (Avg-2DPC, -1DPC,	Baseline (Avg-2DPC, 1DPC)         2DPC (Avg-2DPC, 1DPC)         3DPC (Avg-2DPC, 1DPC, 1DPC)         3DPC (Avg-2DPC, 1DPC, 1DPC)         3DPC (Avg-2DPC, 1DPC, 1DPC, 1DPC, 1DPC)         3DPC (Avg-2DPC, 1DPC,	Baseline (Avg-2DPC, 1DPC)         120 PC         3DPC (Avg-2DPC)         3DPC (Avg-2DPC)         4DPC (Avg-2DPC)         3DPC (Avg-2DPC)         4DPC (Avg-2DPC)         3DPC (Avg	Seyline (Awg-2DPC, 1DPC	Baseline (Awg-2DPC, 1DPC -1DPC)         1DPC -1DPC, 1DPC -1DPC, 1DPC         1DPC -1DPC, 1DPC -1DPC, 1DPC -1DPC -1DPC, 1DPC -1DPC, 1DPC, 1DPC -1DPC, 1DPC, 1DPC -1DPC, 1D	Baseline (Aug2DPC, -1DPC)         3DPC         4DPC         5DPC         6DPC         7DPC         8DPC         4DPC         11DPC         11DPC </td

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

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				Leptospir	eptospira ictero White Blood Cell Count Post Challenge	Vhite Bloo	od Cell Co	unt Post	Challenge					
						Cont	Controls							
Baseline Avg -2DPC, -1DPC, 0DPC)	1DPC	2DPC	ЗБРС	4DPC	SDPC	бРРС	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
	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	8.2	5'9	7.3	13.4	9.4	7.2	8.2	13.4	10.1	1.7	9.7	9.4
	12.2	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	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	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	15.8	14.6	10.7	9.8	7.5	8.6	12.1	9.8	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	4.1	26.4					]	O O				
	7.6	5	7.2	7.8	7.5	7.8	6.2	6.6	8	10.3	10.1	9.9	9.4	9.6
	8.1	8.3	4.2	19						D				
	9.3	6.2	5	10.7	12.6	10.6	13.5	14.5	9.6	14.1	9.9	10	10.1	9.3

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
nallenge			9DPC		442	505	208	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	500	352
Platelet	SC Vaccinates		6DPC		457	645	445	344	435	308	542	393	459	555
ictero			SDPC		667	526	580	374	282	278	214	351	417	515
otospira			4DPC		440	428	424	457	275	264	332	397	529	525
Le			3DPC		476	447	095	349	286	217	386	392	552	483
			2DPC		619	456	425	413	297	298	400	269	386	206
			1DPC		432	475	262	258	380	264	407	482	467	412
		Baseline	(Avg -2DPC, -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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				Ę	otospira	ictero	Platelet	ptospira ictero Platelet Counts Post Challenge	Post C	allenge	_				
							Controls	slo.							
Dog	Baseline (Avg2DPC, -1DPC, 0DPC)	1DPC	2DPC	зорс	4DPC	SDPC	бррс	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
21	534.3	291	315	207	301	341	545	206	529	537	575	434	399	414	410
22	428.7	238	250	168	126	184	261	288	340	412	520	421	369	386	367
23	411.3	374	307	265	289	362	393	361	369	447	546	444	422	583	535
24	344.7	251	130	99.5	116	189	312	497	440	480	618	635	461	658	451
25	266	401	220	146	189	288	483	611	458	466	660	519	427	432	409
26	392	302	213	94.9	84.5	210	361	381	421	444	467	578	513	452	388
27	475.7	399	423	483	413	335	386	437	465	575	469	461	540	372	474
28	411.7	214	93.5	60.5	128	213	307	332	467	612	622	618	495	467	383
29	332	136	101	6.7	11.2					]	D				
30	421.9	204	80.9	53.9	119	231	379	512	549	516	642	494	411	421	427
31	319.3	163	94.4	36.7	11.9					]	D				
32	267	184	55	7.7	88.8	196	257	347	525	430	529	360	337	287	301
D = Dead	P														

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

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

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Isolation of Leptospira from Blood Collected from Dogs Post Challenge

					-			rol Anin							
Dog	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1			+	+	+	+									
2															
3			+	+	+										
4				+	+										
5			+	+	+	+									
6			+	+											
7		+	+	+											
8			+	+	+										
9		+	+	+	+										
10		+		+	+										

DPC= Day post challenge

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<sup>\*</sup>Leptospira was not isolated from blood in any of the SC vaccinates

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

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

DPC – Days post-challenge

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	21DPC	10,12									12							
	00PC   10PC   20PC   40PC   50PC   60PC   70PC   80PC   100PC   110PC   120PC   130PC   140PC   150PC   160PC   180PC   190PC   200PC   210PC									12	12		peve					
	19DPC			10							11,12	10,12	Intermittent minor stool abnormalities observed	CDV				
	18DPC										11,12		ormaliti	signs of				
	17DPC		14								10,12	10,12	ol abno	were not considered clinical signs of CDV				
ogs	16DPC												nor sto	dered				
ted D	15DPC												ttent m	ot consi	ć.			
ccina	14DPC											П	Intermit	were no	infection.			
- Va	13DPC												Ī					
llengo	12DPC	Г										П						
CDV Clinical Signs Observed Post Challenge - Vaccinated Dogs	11DPC	Г																Blank - No Clinical signs observed
od Po	10DPC													ation	its	rTics		signs
Observ	9DPC												50	16 - Excessive Salivation	17 - Chewing gum fits	18 - neuromuscular Tics		Clinical
Signs	SDPC											Ц	14 - Vomiting	Excessi	Chewin	neurom	20 - death	ik - No
s leal	C 7DP	L						27.5		_		Н	14 -	16 -	17 - (	18-	20-	Blan
V Clir	PC 6DF	Н										Н		picon				
8	DPC SD	Н		H			10					Н		M egs				
	DPC 40	Н		-			-			H		Н	Vare	Discha				
	DPC 30	H	H	-						H		Н	n/Leth	Ocular	c	100	-	5
	DPC 2	H										$\parallel$	ression	/Mod.	ydratio	ous st	ery Sto	dy sto
	0DPC 1												1 - Depression/Lethargy	2- Mild/Mod. Ocular Discharge Mucoid	8 - Dehydration	10-Mucous stool	11-watery Stool	12-Bloody stool
	Dog	18	19	20	21	22	23	24	25	26	27	28						

DPC – Days post-challenge

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					ū	CDV Clini	cal Sig	Clinical Signs Observed Post Challenge - Vaccinated Dogs	perved	Post	Challe	nge -	Vacci	nated	Dog	S					
									S	SC Vaccinates	notes										
Dog	22DPC	22DPC   23DPC   24DPC   25DPC   26DPC	24DPC	25DPC	26DPC	-	28DPC	29DPC	30DPC	31DPC	32DPC	33DPC	34DPC	35DPC	36DPC	37DPC	38DPC	39DPC	27DPC   28DPC   29DPC   30DPC   31DPC   32DPC   34DPC   35DPC   36DPC   37DPC   38DPC   39DPC   40DPC   41DPC	1DPC 4	42DPC
18	11													Г				Г			
19																					
20				277																	
21																					
22				10,12													14				
23	10				10	10	10		12											-	
24	30																				
25	37.																			-	
26						10		10	10												
27	11,12		10,12		10,12	10,11,12	12														
28	11	10,12	10,12					10,12				12	12	12		12			12		
	1 - Dep	1 - Depression/Lethargy	/Lethar	AB				14 - Vomiting	niting					Ī	ntermit	ttent m	nor sto	ol abno	Intermittent minor stool abnormalities observed	sobser	ved
	2- Mild	2- Mild/Mod. Ocular Discharge Mucoid	Cular D	Discharg	e Muco	pi		16 - Exce	16 - Excessive Salivation	alivatio	uc			-	were no	ot consi	dered	linical s	were not considered clinical signs of CDV	AQ:	
	3 - Deh	8 - Dehydration						17 - Che	17 - Chewing gum fits	ım fits					infection.	'n.					
	10-Muc	10-Mucous stool	10					18 - neu	18 - neuromuscular Tics	ular Tic	27										
	11-wat	11-watery Stool	-					20 - death	th												
	12-8106	12-Bloody stool	-					Blank -	No Clin	ical sign	Blank - No Clinical signs observed	pavi									

 $DPC-Days\ post-challenge$ 

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

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CPV Post Challenge Daily Observations

	ည္က					
	14D					
	7DPC SDPC 9DPC 10DPC 11DPC 12DPC 13DPC 14DPC					
	12DPC					
	11DPC					
	10DPC					
	9DРС					
trols	SDPC		o			
ated Con	7DPC		၁	-	-	
Non-Vaccinated Controls	6DPC	E,H	B,C,H	B,G,H	B,C,D,F,G,H	
	SDPC			O	H,D	
	3DPC 4DPC 5DPC			Н		
	3DPC					
	2DPC					
	0DPC 1DPC 2DPC	۵				
	0DPC					
	D <sub>og</sub>	1	2	က	4	

	14DPC																	
	13DPC																	
	12DPC																	
	11DPC							E										
	10DPC			E		O												
	9DРС										a							
	SDPC																	
Vaccinates	7DPC																	
Vacc	6DPC			Н														
	SDPC											٥						
	4DPC																	
	3DPC																	
	2DPC													٥				
	1DPC											a						
	0DPC			Q														
	Dog ID	1	2	3	4	5	9	7	8	6	10	11	12	13	14	15	16	1,

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

DPC = Days Post Challenge

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Daily Rectal Temperature (°F)

	,.				
	14DPC	101.2	102.0	Na	Na
	13DPC	101.4	102.4	Na	Na
	12DPC	100.6	101.3	Na	Na
	11DPC	101.4	101.6	Na	Na
	10DPC	100.8	101.5	Na	Na
	9DPC	101.0	101.0	Na	Na
ontrols	SDPC	101.3	101.0	Na	Na
Non-Vaccinated Controls	7DPC	101.3	101.0	Na	Na
Non-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	3	4

_	_	_			_			_	_	_	_								
	14DPC	101.8	102.1	100.8	102.3	101.8	102.0	101.6	101.2	102.1	101.6	102.2	101.9	101.3	101.7	102.3	102.3	101.7	
	13DPC	101.3	101.3	101.4	100.9	101.3	102.7	101.1	101.3	101.8	101.0	102.1	101.8	101.1	100.5	101.7	101.8	101.2	
	12DPC	101.7	101.7	101.3	101.2	101.5	102.5	101.3	101.0	101.4	101.1	101.9	101.4	101.2	101.0	101.3	101.4	101.4	
	11DPC	101.8	101.7	101.0	101.4	101.7	102.4	101.0	101.3	102.3	101.2	102.5	101.6	101.1	100.8	101.4	101.3	101.2	
	10DPC	101.1	101.4	100.9	101.3	101.6	102.3	101.2	101.1	101.7	101.1	101.7	101.3	101.1	101.4	101.2	101.7	101.6	
	9DPC	101.7	101.6	101.2	101.4	101.5	101.8	101.0	101.1	101.3	101.1	102.3	101.2	101.3	100.4	101.8	101.9	101.4	
	8DPC	101.5	101.7	101.4	101.7	101.3	101.5	101.3	101.1	101.5	101.1	102.3	101.0	101.1	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	
Š	6DPC	101.0	101.5	100.6	101.3	101.3	101.1	100.8	100.9	101.1	100.6	101.8	101.3	100.3	101.5	100.8	100.9	100.8	
	SDPC	101.5	101.5	101.1	101.1	101.0	101.6	100.8	101.3	101.0	101.2	102.2	101.8	101.5	101.4	101.4	102.5	101.9	
	4DPC	101.7	101.1	101.3	101.4	101.2	102.0	100.9	101.1	101.2	101.2	102.1	101.4	101.0	101.0	101.6	101.8	101.2	
	3DPC	101.3	101.3	100.8	101.7	101.5	101.5	101.2	101.1	101.0	101.4	101.8	101.5	101.3	101.4	101.0	101.7	102.1	
	2DPC	101.2	101.5	101.0	101.4	101.4	102.1	101.0	101.5	102.1	101.6	10.2	101.4	101.8	101.0	101.1	101.9	102.0	
	1DPC	101.9	100.5	100.5	100.9	101.0	101.9	100.8	100.7	101.6	100.8	101.5	102.2	100.4	101.1	101.2	102.1	101.6	nallenge
	0DPC	101.1	101.1	101.0	100.7	101.0	101.3	100.5	2.66	100.5	101.3	101.3	100.9	6.66	2.66	100.7	100.9	101.8	vs Post Ci
	Cat ID	2	9	7	00	6	10	11	12	13	14	15	16	17	18	19	20	21	DPC = Days Post Challenge

DPC = Days Post Challenge

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Total White Blood Cell Counts (x1000/uL)

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

	$\overline{}$																	
	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	9.61	8.73	8.40	8.17	8.00	7.71	10.70	11.80	17.10	11.0	12.6	7.8	11.8	17.2	14.1	12.9
Vaccinates	SDPC	12.7	10.1	10.2	9.3	9.3	10.0	8.8	10.4	11.2	14.0	10.9	14.7	12.7	14.9	28.6	28.2	14.4
Vacci	4DPC	10.3	9.3	9.4	9.0	6.7	6.6	9.4	13.9	11.0	20.4	10.6	16.0	9.3	14.7	21.9	18.9	12.8
	3DPC	8.4	11.0	9.1	10.0	10.3	12.3	Na	15.3	15.1	Na	12.6	16.0	Na	14.6	20.0	17.4	15.9
	2DPC	11.8	12.7	9.3	10.2	12.8	15.1	9.8	21.8	16.1	17.6	14.5	16.0	9.1	11.0	27.7	18.7	14.3
	1DPC	11.8	10.2	9.0	10.4	12.8	13.7	11.7	18.5	17.6	21.6	17.6	18.5	10.8	14.8	28.2	21.3	11.6
	0DPC	10.2	11.0	13.5	11.9	12.5	12.7	11.3	27.2	7.8	20.4	16.7	21.6	13.6	12.4	37.0	19.0	16.7
	Cat ID	5	9	7	8	6	10	11	12	13	14	15	16	17	18	19	20	21

DPC = Days Post Challenge

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		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 FAID <sub>so</sub> /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	SN
ecal Mat	า-Vaccina	4DPC	2.4	1.5	3.2	3.5
r From Fe	Noi	3DPC	<1.5	<1.5	<1.5	<1.5
CPV Tite		2DPC	<1.5	<1.5	<1.5	<1.5
		1DPC	<1.5	<1.5	<1.5	<1.5
		0DPC	<1.5	<1.5	<1.5	<1.5
		Cat ID	1	2	3	4

_				_			_	_	_	_	_	_	_	_	_	_	_	_
	10DPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
	9DPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	41.5
	SDPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	41.5
	7DPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
	6DPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	41.5
Vaccinates	SDPC	NS	41.5	NS	<1.5	<1.5	NS	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	NS	<1.5
Vacci	4DPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
	3DPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
	2DPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
	1DPC	<1.5	41.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	4.5
	0DPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
	Cat ID	5	9	7	80	6	10	11	12	13	14	15	16	17	18	19	20	21

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

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<b>Study Type</b>	Efficacy
Pertaining to	Canine Parvovirus (CPV)
<b>Study Purpose</b>	To demonstrate effectiveness against CPV
<b>Product Administration</b>	Two doses given at an interval of 28 days were administered
	subcutaneously (SC).
Study Animals	6-week old puppies seropositive for parvovirus, 20 vaccinates
	and 5 non-vaccinated controls.
<b>Challenge Description</b>	Fifty-six days (56) after second vaccination puppies were
	challenged with CPV type 2c strain.
Interval observed after	Puppies were observed for clinical signs daily for 14 days after
challenge	challenge
Results	Dogs were determined affected by the criteria of 9CFR
	113.317(c)(3)(i)
	Number affected:
	Vaccinates: 1/20 (5%)
	Controls: 4/5 (80%)
	Requirements of 9CFR 113.317 (c)(3)(i) were met.
	Raw data:
	Data tables are appended to the end of this summary.
USDA Approval Date	January 31, 2012

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

DPC – Days Post Challenge

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	Dog ID -24DPV1	9 724	11 91	19 23		27 10		Dog ID -24DPV1	1 91	2 64	3 54																	
	0DPV1		4	64		8		ν/1 0DPV1	32																			
	7PV1	4	ω	23	10	6		7PV1	8	23	23	23		16	16 23	16 23 4	16 23 4	16 23 4 4 8 8	16 23 4 8 8 64	16 23 4 8 64 64	16 23 4 8 64 64 16	16 23 4 8 8 64 6 16 2 11	16 23 4 8 8 64 6 16 16 11 11	16 23 4 8 8 64 6 16 16 2 2 19	16 23 4 8 64 64 16 2 2 11 19	16 23 4 8 8 64 6 16 17 11 19 19	16 23 4 8 8 64 64 16 16 2 2 11 19 4 8	16 23 4 8 8 64 64 16 16 2 2 11 19 4 4
Serum Neutrlization Titer	28DPV1 (0DPV2)	<2	<2	<2	<2	<2	Vaccinates	28DPV1 (0DPV2)	<2	<2	2	2	2		<2	22	2	2 2	\$2 \$2 \$2 \$2	\$2 \$2 2 2 2	\$2 \$2 \$2 \$2 \$2 \$2	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	\$2 \$2 \$2 \$2 \$2 \$2 \$2 \$5	\$2 \$2 \$2 \$2 \$2 \$2 \$2 \$2 \$2 \$2 \$2 \$2 \$2 \$	2 2 2 2 2 2 2 2 2 2 2 3 3	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
ization Titer	41DPV1	<2	<2	<2	<2	<2	atec	41DPV1	1024	362	1024	724	•	45	45 <2	45 <2 1024	45 <2 1024 <2	45 42 1024 42 42	45 1024 22 22 45	45 1024 45 45	45 <2 1024 <2 <2 45 45 <2 512	45 1024 <2 <2 <2 45 45 <2 512	45 1024 <2 -2 -45 -45 -45 -42 -512 -2	45 1024 <2 <2 <2 45 45 512 <2 512	45 1024 <2 <2 <2 45 45 <2 512 <2 <2 512 <2 724	45 1024 <2 <2 45 <2 512 <2 512 <2 512 724 4	45 1024 <2 <2 45 <2 512 <2 512 <2 512 <2 4 4 1448	45 -2 1024 -2 -2 45 -2 512 -2 -2 512 -2 -2 -2 -2 -2 -2 -2 -2 -2 -
	56DPV1	<2	<2	<2	<2	<2		56DPV1	11585	6871	5793	19534		4096	4096 512	4096 512 8192	4096 512 8192 2896	4096 512 8192 2896 11585	4096 512 8192 2896 11585 2048	4096 512 8192 2896 11585 2048 2896	4096 512 8192 2896 11585 2048 2896 11585	4096 512 8192 2896 11585 2048 2896 11585 21585 2048 2896	4096 512 8192 2896 11585 2048 2896 11585 9767 11585	4096 512 8192 2896 11585 2048 2296 11585 9767 11585 9767 11585	4096 512 8192 2896 11585 2048 2048 2296 11585 9767 11585 9767 11585	4096 512 8192 2896 11585 2048 2048 2048 21585 9767 11585 9767 11585 23170 8192	4096 512 8192 2896 11585 2048 2048 2296 11585 9767 11585 9767 11585 23170 8192 NO TEST	4096 512 8192 2896 11585 2048 2048 2296 11585 9767 11585 9767 11585 23170 8192 NO TEST 16384
	70DPV1	<2	<2	<2	<2	<2		70DPV1	11585	16384	5793	23170	2	8192	2896	2896 8192	2896 8192 11585	2896 2896 8192 11585	8192 2896 8192 11585 11585 5793	2896 8192 11585 11585 5793 4884	2896 8192 11585 11585 11585 5793 4884 11585	2896 8192 11585 11585 11585 5793 4884 11586 11586	2896 8192 11585 11585 11585 5793 4884 11585 11585 11585	2896 8192 11585 11585 11585 5793 4884 11585 11585 11585 8192	2896 8192 11585 11585 11585 5793 4884 11585 11585 11585 8192 11586	2896 8192 11585 11585 11585 5793 4884 11585 11585 11585 11585 11585 11585	2896 8192 11585 11585 11585 5793 4884 11585 11585 11585 11585 11585 11585 11585	2896 8192 11585 11585 11585 5793 4884 11585 11585 11585 11585 16384 11585 16384 11585
	84DPV1 (0DPC)	<2	<2	<2	<2	<2		84DPV1 (0DPC)	=>23170	16384	6871	=>46341		23170	23170 9767	23170 9767 =>23170	23170 9767 =>23170 =>46341	23170 9767 =>23170 =>46341 11585	23170 9767 =>23170 =>46341 11585 8192	23170 9767 =>23170 =>46341 11585 8192 11585	23170 9767 =>23170 =>46341 11585 8192 11585 16384	23170 9767 =>23170 =>46341 11585 8192 11586 16384 23170	23170 9767 =>23170 =>46341 11585 8192 11586 16384 23170 16384	23170 9767 =>23170 =>46341 11585 8192 11585 16384 23170 16384 11585	23170 9767 =>23170 =>46341 11585 8192 11585 16384 23170 16384 11585	23170 9767 =>23170 =>46341 11585 8192 11585 16384 23170 16384 11585 11585 11585	23170 9767 =>23170 =>46341 11585 8192 11585 16384 23170 16384 11585 11585 11585	23170 9767 =>23170 =>46341 11585 8192 11585 16384 23170 16384 11585 11585 11585 11585 11585

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					Controls	0	Controls						
CatID	-2DPC	-1DPC	0DPC	Average	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC
9	1.24	1.20	1.38	1.27	1.71	1.45	0.80	0.30	0.28	0.74	0.27	Na	Na
⇉	2.24	2.59	2.07	2.30	2.28	2.36	1.82	0.29	0.58	0.69	1.04	1.17	1.27
19	1.57	2.14	1.87	1.86	2.32	2.26	2,42	1.42	0.70	1.59	1.66	1.52	2.11
21	1.67	2.19	2.52	2.13	2.68	1.92	2.31	1.17	0.67	1.75	2.03	1.52	2.
27	2.68	2.26	2.30	2.41	2.29	2.37	2.25	0.92	1.00	1.09	2.04	1.74	2.08
						5	Vaccinatos						
Cat ID	-2DPC	-1DPC	0DPC	Average	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC
_	3.05	3.06	2.74	2.95	2.05	2.25	2.42	2.39	2.66	3.31	2.57	3.01	2.64
2	2.45	2.50	2.34	2.43	3.32	3.05	3.27	3.03	2.73	3.20	3.23	2.92	3.28
3	2.09	2.40	2.34	2.28	2.42	2.46	2.32	1.65	1.73	2.38	2.16	2.42	2.5
4	1.10	1.59	2.46	1.72	3.23	2.45	2.91	2.03	2.75	2.34	2.41	2.87	2.66
5	0.62	0.96	1.16	0.91	1.23	1.32	1.14	1.26	1.19	1.57	1.49	1.36	1.0
6	1.43	1.84	1.73	1.67	1.84	1.55	1.16	1.79	1.62	2.44	1.97	2.32	2.24
7	1.23	1.22	1.18	1.21	1.18	1.51	1.53	1.68	1.52	1.81	0.22	1.67	1.91
8	2.07	1.89	2.00	1.99	1.81	1.93	1.78	1.52	1.64	2.52	2.23	2.51	2.59
10	2.74	2.80	3.27	2.94	1.93	2.43	2.56	3.01	2.65	2.44	2.65	2.64	2.83
13	1.26	2.25	2.24	1.92	2.43	1.88	2.57	2.39	2.57	3.09	3.22	3.24	3.17
14	2.17	2.24	3.02	2.48	3.57	3.62	3.76	3.28	3.07	3.66	4.10	4.18	4.57
15	2.21	2.30	2.66	2.39	3.10	2.81	3.04	2.85	2.98	3.29	2.51	0.93	2.71
16	1.68	2.54	2.06	2.09	2.56	2.08	3.35	2.83	2.35	3.13	2.90	2.27	3.24
17	2.25	2.14	2.11	2.17	2.42	2.84	2.62	2.93	2.69	3.04	2.78	1.34	2.59
18	2.06	2.82	2.50	2.46	2.97	2.48	2.62	3.05	3.04	3.98	3.27	2.26	3.98
20	1.83	2.11	2.05	2.00	2.58	2.22	2.39	2.50	1.73	1.98	2.12	2.28	2.35
22	3.80	3.05	3.35	3.40	3.96	3.18	3.38	3.75	2.36	2.42	3.93	3.23	3.34
23	0.84	1.46	1.51	1.27	1.63	1.35	1.47	1.45	1.29	1.72	1.53	1.44	1.14
24	0.97	2.04	2.32	1.78	2.09	2.24	2.67	2.03	2.03	2.70	2.46	2.68	2.86
	CVC	2 68	2 15	2 42	2 68	280	3 56	3 56	2 52	2 46	2 57	3 61	2 50

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7×g 17	משמה	וחשכ	שחומר	3DPC	Non-Vacci	Non-Vaccinated Controls	1	┑	אַרור	$\dashv$	SDPC
Dog ID	102.0	102.0	2DPC 102.6	3DPC 102.9	4DPC 103.2	5DPC 104.6	6DPC	$\neg \vdash$	7DPC	7DPC SDPC	+
<del>1</del>	102.6	102.9	102.6	102.6	103.1	103.4	102.8	$\neg$	102.2		101.3
19	102.5	102.8	102.1	102.3	101.9	103.8	102.3	$\neg$	102.4		101.6
21	102.2	102.3	101.3	101.4	102.0	103.4	102.0	$\neg$	101.8	$\dashv$	101.5
27	102.2	102.1	102.1	102.7	102.5	102.8	103.0		102.4	Н	100.9
					:			1			
					Vac	v accunates	i	1		+	
Dog ID	0DPC	1DPC	2DPC	3DPC	4DPC	SDPC	6DPC	l	7DPC	7DPC 8DPC	_
1	101.9	102.0	101.9	101.9	101.7	102.0	101.5		101.9	101.9 101.3	-
2	102.7	103.5	103.1	103.1	103.5	102.3	103.1		102.9		102.4
ယ	103.0	103.0	102.5	102.2	102.7	102.7	103.1	. I	103.0	$\dashv$	102.1
4	101.6	102.4	102.3	102.1	102.4	102.1	103.4		102.7	102.7 102.1	102.1
5	103.5	103.4	103.2	103.3	103.5	102.6	102.8	_ I	103.4	$\dashv$	102.8
6	102.7	102.6	101.7	102.8	102.4	102.4	102.8		102.7	Н	102.2
7	101.7	102.5	102.5	103.3	103.0	103.1	103.1		103.1		102.9
8	102.7	102.9	102.5	102.4	102.6	102.2	102.2		102.5		101.7
10	103.1	103.3	102.3	102.8	103.0	102.5	102.2	1	102.7		102.8
13	103.0	102.5	102.8	102.2	103.2	102.6	102.7	l i	103.0	103.0 102.4	102.4
14	102.3	102.8	102.4	102.4	102.7	102.4	102.6		102.4		102.0
15	102.5	102.7	102.3	102.0	102.8	102.2	102.4		102.4		101.9
16	101.7	102.5	102.8	101.9	102.5	102.1	102.1		101.9		
17	101.9	102.8	102.3	102.6	102.7	102.1	102.0		101.9	101.9 102.0	102.0
18	102.2	102.5	102.1	101.5	102.3	102.6	102.0		102.0		101.9
20	102.2	101.9	101.9	102.0	102.2	101.8	101.8		101.9		101.6
22	102.7	102.9	102.4	101.8	102.8	102.5	102.5		102.8		102.0
23	102.5	102.8	102.7	102.7	103.2	102.4	102.7		103.1	103.1 102.1	
24	103.3	103.1	102.6	102.2	102.5	102.4	102.2		102.2		102.1
	102.2	1.201	102.0	102.4	102.2	102.2	102.0		102.0	102.0 101.8	101.8

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Positive For CPV	28	24	23	22	20	18	17	16	15	14	13	10	8	7	6	5	4	3	2	1	CatID		27	21	19	11	9	CatID	
		≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤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	0DPC	
>1.3 log® FALD@/mL	≤1.5	≤1.5	<1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.6	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.8	≤1.5	1DPC		≤1.5	≤1.5	≤1.5	≤1.8	≤1.5	1DPC	
50 mL	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤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		s1.5	≤1.5	≤1.5	≤1.5	≤1.5	2DPC	
	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	3DPC		s1.5	≤1.8	≤1.5	≤1.5	≤1.5	3DPC	
	<1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	5.1≥	≤1.5	≤1.5	≤1.5	4DPC	Vaco	≤2.8	4.3	2.5	5.5	≤2.5	4DPC	Col
	≤2.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	5DPC	Vaccinates	5.2	4.7	4.2	7.2	6.6	5DPC	Controls
	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	6DPC		7.4	6.3	7.5	7.5	7.6	6DPC	
	≤2.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	7DPC		6.6	6.8	7.6	≥8.5	5.2	7DPC	
	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	<1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	8DPC		5.2	≤2.8	4.2	≥8.6	≥9.2	8DPC	
	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	9DPC		≤3.0	4.5	4	≥7.6	Na	9DPC	
	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	10DPC		≤1.5	3.6	≤1.5	6.6	Na	10DPC	

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

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Study Type	
Demonstrate safety of product under typical use controlled in the study. From these dogs 234 we age or younger, at first vaccination. Three geograph represented.    Challenge Description   NA	
Two doses were administered subcutaneously approveeks apart.	
weeks apart.  A total of 675 dogs, privately owned and from comwere enrolled in the study. From these dogs 234 wage or younger, at first vaccination. Three geographerepresented.  NA  Interval observed after challenge  Results  Results  No observed adverse events:  Number of Animals  No observed adverse events:  1 Diarrhea-one day of loose stools  Heavy Breathing  Death-Hit by Car * 1  Death-depression, decreased appetite, weight loss **  Lameness (leg cramp) * 1  Decreased appetite, weight loss, diarrhea, and dehydration *  Gastroenteritis (vomiting) * 2  Laceration * 1  Prolapsed nictitan gland * 7  Pyoderma * 5  *Affirmed by study investigator to have cause othe vaccination  **Cause of death was not determined by study investigator.	
A total of 675 dogs, privately owned and from comwere enrolled in the study. From these dogs 234 wage or younger, at first vaccination. Three geograph represented.  NA  Interval observed after challenge  Results  No observed adverse events:  Number of Animals  No observed adverse events:  1  Diarrhea-one day of loose stools  Heavy Breathing  Death-Hit by Car * 1  Death-depression, decreased appetite, weight loss **  Lameness (leg cramp) * 1  Decreased appetite, weight loss **  Lameness (leg cramp) * 1  Decreased appetite, weight loss, diarrhea, and dehydration *  Gastroenteritis (vomiting) * 2  Laceration * 1  Prolapsed nictitan gland * 7  Pyoderma * 5  *Affirmed by study investigator to have cause othe vaccination  **Cause of death was not determined by study investigator to have cause othe vaccination  **Cause of death was not determined by study investigator to have cause othe vaccination	roximately two
were enrolled in the study. From these dogs 234 wage or younger, at first vaccination. Three geograph represented.  NA  Interval observed after challenge  Results  No observed adverse events:  Number of Animals  No observed adverse events:  Number of Animals  No observed adverse events  Injection Site Lesion  Diarrhea-one day of loose stools  Heavy Breathing  Death-Hit by Car * 1  Death-depression, decreased appetite, weight loss **  Lameness (leg cramp) * 1  Decreased appetite, weight loss, diarrhea, and dehydration *  Gastroenteritis (vomiting) * 2  Laceration * 1  Prolapsed nictitan gland * 7  Pyoderma * 5  *Affirmed by study investigator to have cause othe vaccination  **Cause of death was not determined by study investigator.	
age or younger, at first vaccination. Three geograph represented.  NA  Interval observed after challenge  Results  Animals were observed 30 minutes after each vaccination.  Frequency of adverse events:  Number of Animals  No observed adverse events  Injection Site Lesion  Diarrhea-one day of loose stools  Heavy Breathing  Death-Hit by Car *  Death-depression, decreased appetite, weight loss **  Lameness (leg cramp) *  Lameness (leg cramp) *  Decreased appetite, weight loss, diarrhea, and dehydration *  Gastroenteritis (vomiting) *  Laceration *  Prolapsed nictitan gland *  Pyoderma *  *Affirmed by study investigator to have cause othe vaccination  **Cause of death was not determined by study investigator.	mmercial kennels
represented.  Challenge Description Interval observed after challenge Results  Frequency of adverse events:  Number of Animals  No observed adverse events:  Number of Animals  No observed adverse events:  Number of Animals  No observed adverse events:  Property of adverse events:  Number of Animals  No observed adverse events:  Number of Animals  No observed adverse events:  Poath-derous of loose stools  Heavy Breathing 1  Death-Hit by Car * 1  Death-depression, decreased appetite, weight loss **  Lameness (leg cramp) * 1  Decreased appetite, weight loss, diarrhea, and 4  dehydration *  Gastroenteritis (vomiting) * 2  Laceration * 1  Prolapsed nictitan gland * 7  Pyoderma * 5  *Affirmed by study investigator to have cause othe vaccination  **Cause of death was not determined by study investigator.	vere 6 weeks of
NA	ohical sites were
Interval observed after challenge  Results  Animals were observed 30 minutes after each vaccination.  Frequency of adverse events:  Number of Animals  No observed adverse events 628  Injection Site Lesion 1  Diarrhea-one day of loose stools  Heavy Breathing 1  Death-Hit by Car * 1  Death-depression, decreased appetite, weight loss **  Lameness (leg cramp) * 1  Decreased appetite, weight loss, diarrhea, and dehydration *  Gastroenteritis (vomiting) * 2  Laceration * 1  Prolapsed nictitan gland * 7  Pyoderma * 5  *Affirmed by study investigator to have cause othe vaccination  **Cause of death was not determined by study investigator.	
Interval observed after challenge  Results  Animals were observed 30 minutes after each vaccination.  Frequency of adverse events:  Number of Animals  No observed adverse events  Injection Site Lesion Diarrhea-one day of loose stools Heavy Breathing Death-Hit by Car * 1 Death-depression, decreased appetite, weight loss **  Lameness (leg cramp) * 1 Decreased appetite, weight loss, diarrhea, and dehydration * Gastroenteritis (vomiting) * 2 Laceration * 1 Prolapsed nictitan gland * 7 Pyoderma * 5  *Affirmed by study investigator to have cause othe vaccination **Cause of death was not determined by study investigator.	
Trequency of adverse events:   Number of Animals	cination and daily
Number of Animals	·
No observed adverse events  Injection Site Lesion  Diarrhea-one day of loose stools  Heavy Breathing  Death-Hit by Car * 1  Death-depression, decreased appetite, weight loss **  Lameness (leg cramp) * 1  Decreased appetite, weight loss, diarrhea, and dehydration *  Gastroenteritis (vomiting) * 2  Laceration * 1  Prolapsed nictitan gland * 7  Pyoderma * 5  *Affirmed by study investigator to have cause othe vaccination  **Cause of death was not determined by study investigator.	
No observed adverse events    No observed adverse events   628	
No observed adverse events  Injection Site Lesion  Diarrhea-one day of loose stools  Heavy Breathing  Death-Hit by Car * 1  Death-depression, decreased appetite, weight loss **  Lameness (leg cramp) * 1  Decreased appetite, weight loss, diarrhea, and dehydration *  Gastroenteritis (vomiting) * 2  Laceration * 1  Prolapsed nictitan gland * 7  Pyoderma * 5  *Affirmed by study investigator to have cause othe vaccination  **Cause of death was not determined by study investigator.	Percent of
Injection Site Lesion  Diarrhea-one day of loose stools  Heavy Breathing  Death-Hit by Car * 1  Death-depression, decreased appetite, weight loss **  Lameness (leg cramp) * 1  Decreased appetite, weight loss, diarrhea, and dehydration *  Gastroenteritis (vomiting) * 2  Laceration * 1  Prolapsed nictitan gland * 7  Pyoderma * 5  *Affirmed by study investigator to have cause othe vaccination  **Cause of death was not determined by study investigator.	Animals
Diarrhea-one day of loose stools  Heavy Breathing  Death-Hit by Car * 1  Death-depression, decreased appetite, weight loss **  Lameness (leg cramp) * 1  Decreased appetite, weight loss, diarrhea, and dehydration *  Gastroenteritis (vomiting) * 2  Laceration * 1  Prolapsed nictitan gland * 7  Pyoderma * 5  *Affirmed by study investigator to have cause othe vaccination  **Cause of death was not determined by study investigator.	93.0%
Diarrhea-one day of loose stools  Heavy Breathing  Death-Hit by Car * 1  Death-depression, decreased appetite, weight loss **  Lameness (leg cramp) * 1  Decreased appetite, weight loss, diarrhea, and dehydration *  Gastroenteritis (vomiting) * 2  Laceration * 1  Prolapsed nictitan gland * 7  Pyoderma * 5  *Affirmed by study investigator to have cause othe vaccination  **Cause of death was not determined by study investigator.	0.1%
stools  Heavy Breathing  Death-Hit by Car * 1  Death-depression, decreased appetite, weight loss **  Lameness (leg cramp) * 1  Decreased appetite, weight loss, diarrhea, and 4 dehydration *  Gastroenteritis (vomiting) * 2  Laceration * 1  Prolapsed nictitan gland * 7  Pyoderma * 5  *Affirmed by study investigator to have cause othe vaccination  **Cause of death was not determined by study investigator.	2 424
Heavy Breathing  Death-Hit by Car * 1  Death-depression, decreased appetite, weight loss **  Lameness (leg cramp) * 1  Decreased appetite, weight loss, diarrhea, and 4 dehydration *  Gastroenteritis (vomiting) * 2  Laceration * 1  Prolapsed nictitan gland * 7  Pyoderma * 5  *Affirmed by study investigator to have cause othe vaccination  **Cause of death was not determined by study investigator.	3.4%
Death-depression, decreased appetite, weight loss **  Lameness (leg cramp) * 1  Decreased appetite, weight loss, diarrhea, and 4 dehydration *  Gastroenteritis (vomiting) * 2  Laceration * 1  Prolapsed nictitan gland * 7  Pyoderma * 5  *Affirmed by study investigator to have cause othe vaccination  **Cause of death was not determined by study investigator.	0.1%
Death-depression, decreased appetite, weight loss **  Lameness (leg cramp) * 1  Decreased appetite, weight loss, diarrhea, and 4 dehydration *  Gastroenteritis (vomiting) * 2  Laceration * 1  Prolapsed nictitan gland * 7  Pyoderma * 5  *Affirmed by study investigator to have cause othe vaccination  **Cause of death was not determined by study investigator.	0.1%
appetite, weight loss **  Lameness (leg cramp) * 1  Decreased appetite, weight loss, diarrhea, and 4 dehydration *  Gastroenteritis (vomiting) * 2  Laceration * 1  Prolapsed nictitan gland * 7  Pyoderma * 5  *Affirmed by study investigator to have cause othe vaccination **Cause of death was not determined by study investigator.	0.404
Lameness (leg cramp) * 1  Decreased appetite, weight loss, diarrhea, and 4 dehydration *  Gastroenteritis (vomiting) * 2  Laceration * 1  Prolapsed nictitan gland * 7  Pyoderma * 5  *Affirmed by study investigator to have cause othe vaccination **Cause of death was not determined by study investigator.	0.1%
Decreased appetite, weight loss, diarrhea, and 4 dehydration *  Gastroenteritis (vomiting) * 2  Laceration * 1  Prolapsed nictitan gland * 7  Pyoderma * 5  *Affirmed by study investigator to have cause othe vaccination **Cause of death was not determined by study investigator.	0.1%
loss, diarrhea, and dehydration *  Gastroenteritis (vomiting) * 2  Laceration * 1  Prolapsed nictitan gland * 7  Pyoderma * 5  *Affirmed by study investigator to have cause othe vaccination **Cause of death was not determined by study investigator.	
dehydration * Gastroenteritis (vomiting) * 2  Laceration * 1  Prolapsed nictitan gland * 7  Pyoderma * 5  *Affirmed by study investigator to have cause othe vaccination **Cause of death was not determined by study investigator.	0.6%
Gastroenteritis (vomiting) * 2  Laceration * 1  Prolapsed nictitan gland * 7  Pyoderma * 5  *Affirmed by study investigator to have cause othe vaccination  **Cause of death was not determined by study investigator.	
Prolapsed nictitan gland * 7 Pyoderma * 5  *Affirmed by study investigator to have cause othe vaccination **Cause of death was not determined by study investigator.	0.3%
*Affirmed by study investigator to have cause othe vaccination **Cause of death was not determined by study investigator.	0.1%
*Affirmed by study investigator to have cause othe vaccination **Cause of death was not determined by study investigator.	1.0%
*Affirmed by study investigator to have cause othe vaccination **Cause of death was not determined by study investigator.	0.7%
vaccination  **Cause of death was not determined by study invo	0.7,70
vaccination  **Cause of death was not determined by study invo	er than
**Cause of death was not determined by study invo	
	vestigator, Signs
Tributa a sulfa mana asam o anyo	
The injection site lesion was detected after the second	ond vaccination
and resolved within 15 days.	
USDA Approval Date 13 Jan 2011	
USDA Approval Date 13 Jan 2011	
The injection site lesion was detected after the second	vestigator. Signs s later.

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