

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

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1599.24
True Name	Canine Distemper-Adenovirus Type 2-Coronavirus- Parainfluenza-Parvovirus Vaccine, Modified Live & Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Canine Spectra 6 - Peak Marketing Solo-Jec 6 - 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 Canin													
Interval observed after	Puppies were ob	served for 21 d	ays after challenge	for clinical										
challenge	signs.	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	ODPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC 7	DPC 8D	PC 9D	PC 10D	PC 11DF	C 12DPC	13DPC	14DPC	15DPC :	L6DP(
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***					NA					
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	i						
25	SC Vac																
26	SC Vac																
27	SC Vac																
28	SC Vac																
29	SC Vac								6						6		
	1 - Depressi	on/Letl	nargy			6 - Serous od	ular discharge	15	- Exces	sive Sal	vation		23 - 0	ther			
	3- Dehydration				7 - Mild/Mo	derate mucopurulent						* Icte	ric Lum	bar only			
	4 - Mild/Moderate Conjunctiviti		nctivitis		Ocular Disch	arge	20 - Petechial Pain /					** Ict	eric lum	bar and	ears		
	5 - Severe Co	onjunc	tivitis			13 - Vomitin	Ecchymotic ***- moribund an					nd and e	nd euthanization				
					al signs ob	served in any	group after 16DPC	22	! - Death	1			DPC -	Days po	st challe	nge	

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Study Type	Efficacy
Pertaining to	Canine Adenovirus Type II
Study Purpose	To demonstrate effectiveness against Canine Adenovirus Type II (CAV2)
<b>Product Administration</b>	Two doses were administered subcutaneously 21 days apart
Study Animals	Twenty-two (22) 6-week-old puppies seronegative for CAV2 were randomly sorted into one group of 11 SC vaccinates and one group of 11 controls.
<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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	10DPC 11DPd12DPd13DPd14DPd15DPd16DPd17DPd18DPd19DPd20DPd21DPd						1		1											1 1					pava
	18DPC	L					1													1					Blank - No Clinical signs observed
	C17DPC	L																							al sign
	C16DP	L							1				L							1				ance	Clinica
	C15DP	L	L			L		1,2	1				L						L					7-Inappetance	k - No
	C14DP	L							1				L											7-Ina	Blan
e e	C13DP	L				L		1,2			L		L							-					
allen.	C12DP	L							1		1		L												argy
충	11DP	L											L												n/leth
d Po	10DPC			1				2,4	1															guir	ression
serve	9DPC	2	2	1	2	1	1	1	1	4	1,2	1									1,2			5 -Retching	6 - depression/lethargy
ns Of	8DPC	2	1,2	1	1,2,	1		1	1	4	1	1			1					1	1				
CAV2 Clinical Signs Observed Post Challenge	7DPC		1,2	1	1,2,4	1,4		1,2,4,5,6	1	1	1	1,2							1	1	1				
W2 Cli	6DPC	1,2	1,2	1,2	1,2	1	4	1,2,4	1,6	1	1	1,2						1	1	1	1			guiz	hing
8	SDPC	-	1	1	1,2	1		1	1,2		1				1					1	1			3- Sneezing	4 - Coughing
	4DPC	Г				Г	2	П	1		1	2	Г		П				Г	1					1
	ЗОРС	Г				Г		П	1,2				Г						Г					u	
	2DPC	Г							1,2				Г							1				scharg	charge
	1DPC								1											1				llar Di	al Dis
	ODPC 1DPC 2DPC 3DPC 4DPC																							1 - Ocular Discharge	2- Nasal Discharge
	Group	Control	Control	Control	Control	Control	SC	SC	SC	SC															
DPC - Day	Dog	_	2	L	4	2	9	7	00	6	10	11	23	24	25	26	27	28	53	30	31	32	33		

DPC - Days Post Challenge

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	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	Н	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										Г													
	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	
<b>Challenge Description</b>	
Interval observed after	
challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance. Study data, however, are no longer available.
USDA Approval Date	December 3, 1984

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

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## CPI Serum Neutralization Antibody Titers

					Controls					
Dog	0DPV1	14DPV1	0DPV2	7DPV2	14DPV2 (w)	14DPV2	21DPV2	7DPC	14DPC	21DPC
1	<2	<2	<2	<2	<2	<2	<2	2	28	65
2	<2	<2	<2	<2	<2	<2	<2	1	99	182
3	<2	<2	<2	<2	<2	<2	<2	1	81	280
4	<2	<2	2	<2	<2	<2	<2	3	46	221
5	<2	<2	<2	<2	<2	<2	<2	2	71	289
6	<2	<2	<2	<2	<2	<2	<2	4	64	182

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

DPV - Days Post Vaccination

DPC - Days Post Challenge

A titer of <2 is considered seronegative

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

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

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

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

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

Study Type	Efficacy												
Pertaining to	Canine Distemp	er Virus (CDV)	)										
Study Purpose	To demonstrate	effectiveness ag	gainst CDV										
<b>Product Administration</b>	Two doses were	administered st	ubcutaneously 21	days apart									
Study Animals	Seventeen (17) 6	-week-old pup	pies seronegative f	for CDV									
	were randomly sone group of 6 c	_	oup of 11 SC vacci	nates and									
<b>Challenge Description</b>	21 days after sec CDV.	ond vaccination	n all dogs were cha	allenged with									
Interval observed after	Dogs were obser	ved for 42 days	s after challenge fo	or clinical signs									
challenge	of CDV.												
Results	The study was so (b)(3) (i-ii)	atisfactory per t	he 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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	10DPC	20	20	2,8,10,12	20	10,12	2,8,10,12														
	9DPC	20	50	1,8,10,11,12	2,8,17	2,10,12	2,10,12	31-42DPC	56	3	20	20	20		20		מ אפום ווסר				
ø	8DPC	20	8,10,12,14,16,17,18, Euth	8,10,11,14	1,2,8,10,12	10,11	12,2	30DPC	2	27	20	20	20	10,12	20	1000	intermittent millor stool abnormalities observed were not	considered chillical signs of cov linection.			
CDV Clinical Signs Observed Post Challenge - Control Dogs	7DPC	10,12,16,17,Euth	14	14	10,12		11,12	28-24DPC	00	07	20	20	20		20		mremment minor st	considered cillings			
st Challeng	6DPC	2,12	1,2,10,12	12	10	10,12	2,10,12	270PC	5	23	50	20	20	10,12	20						
bserved Po:	SDPC	10	2,10,12	10,12	2,10,12		2,10,12	16DPC-26DPC	ç	3	20	20	20		20		Salivation	um fits	cular Tics		Annual Management of some desired
cal Signs O	4DPC	10,11,12	10				2,12	15DPC	1	3	20	20	20	11,12	20	14 - Vomiting	16 - Excessive Salivation	17 - Chewing gum fits	18 - neuromuscular Tics	20 - death	Single Market
CDV Clini	ЗОРС	10,12,18	2,10,12	2,10,12	2,10,12			14DPC	5	3	20	1,8,9,10,12	20		20						
	2DPC	10,12,18						13DPC	ç	22	20	8,10,11	20	2,11	20		2- Mild/Mod. Ocular Discharge Mucoid				
	1DPC							12DPC	۶	2	20	1,8,10	20		1,2,8,12	on/Letharg	J. Ocular Dis	ion	stool	loo	-
	ODPC							110PC	,	3	50	8,10,12	20	8,10,12,14	1,2,8,10,12	1 - Depression/Lethargy	2- Mild/Moc	8 - Dehydration	10-Mucous stoo	11-watery Stool	12 Blands stand
	Dog	1	2:	m	4	ΙŌ	ú	DCie		†	53	ñ	4	NO.	9		. •				ĺ

DPC – Days Post Challenge

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	21DPC	10,12									12							
	20DPC									12	12		peve					
	19DPC			10							11,12	10,12	es obse	CDV				
	18DPC										11,12		ormaliti	signs of				
	17DPC		14								10,12	10,12	ol abno	linical s				
ogs	16DPC												nor sto	dered				
ted D	15DPC	Γ										П	tent mi	t consid	ď			
ccina	14DPC	Γ										П	Intermittent minor stool abnormalities observed	were not considered clinical signs of CDV	infection.			
e - Va	13DPC												Ī					
lleng	12DPC	Γ																n
CDV Clinical Signs Observed Post Challenge - Vaccinated Dogs	SC Vaccinates  50 Vaccinates  50 Vaccinates  51 Vaccinates																	Blank - No Clinical signs observed
ved Po	3C V													ation	its	rTics		signs
Observ	9DPC												50	16 - Excessive Salivation	17 - Chewing gum fits	18 - neuromuscular Tics		Clinical
gns	SDPC	L										Ц	14 - Vomiting	xcessi	hewin	euron	20 - death	k - No
cal S	7DPC	L										Ц	14 - V	16 - E	17.0	18- 7	20 - 0	Blank
Gin	6DPC													pid				
9	SDPC													Mucc				
	4DPC						10							harge				
	3DPC	Γ										П	hargy	or Disc				
	SDPC	Г	Г							Г	Г	П	u/Let	Ocula	uo	loo	100	loc
	DPC	T		Г						Г			ressic	/Mod	ydrati	s sno	ery Sto	ody sto
	00PC 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						

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Clinical Signs Observed Post Challenge - Vaccinated Dogs		28DPC 29DPC 30DPC 31DPC 32DPC 33DPC 34DPC 35DPC 35DPC 37DPC 37DPC 39DPC 40DPC 42DPC 42DPC					14						12 12	Intermittent minor stool abnormalities observed	were not considered clinical signs of CDV	infection.			
accinat		DPC 35DP	L										12 12						
Je - Ve		3DPC 34											12 ;						- Property
Challer	notes	32DPC 3													u		57		Black Mo Clinical since observed
Post	SC Vaccinates	31DPC													16 - Excessive Salivation	um fits	18 - neuromuscular Tics		ieni ein
served		30DPC						12			10			niting	essive S	g guiwa	uromus	ath	Min City
ns Ob		29DPC									10		10,12	14 - Vomiting	16 - Exc	17 - Chewing gum fits	18 - neu	20 - death	Displant
sal Sig		28DPC						10				12							
CDV Clinic		27DPC						10			10	10,11,12			p				
8		26DPC						10				10,12			Muco				
		25DPC					10,12							A	scharge				
		24DPC										10,12	10,12	Letharg	cular Di		10		
		22DPC   23DPC   24DPC   25DPC   26DPC											10,12	1 - Depression/Lethargy	2- Mild/Mod. Ocular Discharge Mucoid	8 - Dehydration	10-Mucous stool	11-watery Stool	In Blandward
		22DPC	11					10				11,12	11	1 - Depr	2- Mild	8 - Dehy	10-Muc	11-wate	13.010.01
		Dog	18	19	20	21	22	23	24	25	26	27	28						

DPC – Days Post Challenge

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

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CPV Post Challenge Daily Observations

_			_	_		,	_		_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	
	14DPC							14DPC																	
	13DPC							13DPC																	
	12DPC							12DPC																	
	11DPC							11DPC							E										
	10DPC							10DPC			E		0												
	9DРС							9DРС										D							
trols	SDPC		0					SDPC																	
ated Con	ЛЪРС		С	-	_		Vaccinates	7DPC																	
Non-Vaccinated Controls	6DPC	E,H	B,C,H	B,G,H	B,C,D,F,G,H		Vacc	6DPC			Ŧ														
	SDPC			۵	G,H			SDPC											Q						
	4DPC			I				4DPC																	
	3DPC							3DPC																	
	2DPC							2DPC													D				
	1DPC	٥						1DPC											D						
	0DPC							0DPC			O														
	Dog D	1	2	က	4			D <sub>og</sub>	1	2	3	4	2	9	7	8	6	10	11	12	13	14	15	16	17

DPC = Days Post Challenge

H - Vomiting I - Death

E - Watery Stool F - Bloody Stool G - Anorexia

B - Lethargy C. Dehydration D - Mucous Stool

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Daily Rectal Temperature (°F)

	_				$\overline{}$
	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	8	4

ODPC   1DPC   2DPC   4DPC   5DPC	2DPC   3DPC   4DPC	3DPC 4DPC	4DPC	l ⊢	SDPC	Va 6DPC	Vaccinates	SDPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
101.9 101.2 101.3 101.7 101.5	101.2 101.3 101.7 101.5	101.3 101.7 101.5	101.7 101.5	101.5	╢	101.0	101.0	101.5	101.7	101.1	101.8	101.7	101.3	101.8
101.1 100.5 101.5 101.3 101.1 101.5	101.5 101.3 101.1	101.3 101.1	101.1		101.5	101.5	101.3	101.7	101.6	101.4	101.7	101.7	101.3	102.1
101.0 100.5 101.0 100.8 101.3 101.1	101.0 100.8 101.3	100.8 101.3	101.3		101.1	 100.6	100.5	101.4	101.2	100.9	101.0	101.3	101.4	100.8
100.7 100.9 101.4 101.7 101.4 101.1	101.4 101.7 101.4	101.7 101.4	101.4		101.1	101.3	101.3	101.7	101.4	101.3	101.4	101.2	100.9	102.3
101.0 101.0 101.4 101.5 101.2 101.0	101.4 101.5 101.2	101.5 101.2	101.2		101.0	101.3	101.1	101.3	101.5	101.6	101.7	101.5	101.3	101.8
101.3 101.9 102.1 101.5 102.0 101.6	102.1 101.5 102.0	101.5 102.0	102.0		101.6	101.1	101.4	101.5	101.8	102.3	102.4	102.5	102.7	102.0
100.5 100.8 101.0 101.2 100.9 100.8	101.0 101.2 100.9	101.2 100.9	100.9		100.8	100.8	101.2	101.3	101.0	101.2	101.0	101.3	101.1	101.6
99.7 100.7 101.5 101.1 101.1 101.3	101.5 101.1 101.1	101.1 101.1	101.1		101.3	100.9	101.0	101.1	101.1	101.1	101.3	101.0	101.3	101.2
100.5 101.6 102.1 101.0 101.2 101.0	102.1 101.0 101.2	101.0 101.2	101.2		101.0	101.1	100.9	101.5	101.3	101.7	102.3	101.4	101.8	102.1
101.3 100.8 101.6 101.4 101.2 101.2	101.6 101.4 101.2	101.4 101.2	101.2	Н	101.2	100.6	100.9	101.1	101.1	101.1	101.2	101.1	101.0	101.6
101.3   101.5   10.2   101.8   102.1   102.2	10.2 101.8 102.1	101.8 102.1	102.1		102.2	101.8	101.5	102.3	102.3	101.7	102.5	101.9	102.1	102.2
100.9   102.2   101.4   101.5   101.4   101.8	101.4 101.5 101.4	101.5 101.4	101.4		101.8	101.3	101.5	101.0	101.2	101.3	101.6	101.4	101.8	101.9
99.9 100.4 101.8 101.3 101.0 101.5	101.8 101.3 101.0	101.3 101.0	101.0		101.5	100.3	101.7	101.1	101.3	101.1	101.1	101.2	101.1	101.3
99.7   101.1   101.0   101.4   101.0   101.4	101.0 101.4 101.0	101.4 101.0	101.0		101.4	101.5	100.7	100.7	100.4	101.4	100.8	101.0	100.5	101.7
100.7   101.2   101.1   101.0   101.6   101.4	101.1 101.0 101.6	101.0 101.6	101.6		101.4	100.8	100.7	101.4	101.8	101.2	101.4	101.3	101.7	102.3
100.9 102.1 101.9 101.7 101.8 102.5	101.9 101.7 101.8	101.7 101.8	101.8	Н	102.5	100.9	101.3	101.6	101.9	101.7	101.3	101.4	101.8	102.3
101.8   101.6   102.0   102.1   101.2   101.9	102.0 102.1 101.2	102.1 101.2	101.2		101.9	100.8	101.3	101.7	101.4	101.6	101.2	101.4	101.2	101.7
DPC = Days Post Challenge	allenge													

DPC = Days Post Challenge

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Total White Blood Cell Counts (x1000/uL)

				Non	-Vaccina	Non-Vaccinated Controls	trols				
CatID	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
	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	5DPC	12.7	10.1	10.2	9.3	9.3	10.0	8.8	10.4	11.2	14.0	10.9	14.7	12.7	14.9	28.6	28.2	14.4
Vacci	4DPC	10.3	9.3	9.4	9.0	9.7	6.6	9.4	13.9	11.0	20.4	10.6	16.0	9.3	14.7	21.9	18.9	12.8
	3DPC	8.4	11.0	9.1	10.0	10.3	12.3	Na	15.3	15.1	Na	12.6	16.0	Na	14.6	20.0	17.4	15.9
	2DPC	11.8	12.7	9.3	10.2	12.8	15.1	9.8	21.8	16.1	17.6	14.5	16.0	9.1	11.0	27.7	18.7	14.3
	1DPC	11.8	10.2	9.0	10.4	12.8	13.7	11.7	18.5	17.6	21.6	17.6	18.5	10.8	14.8	28.2	21.3	11.6
	0DPC	10.2	11.0	13.5	11.9	12.5	12.7	11.3	27.2	7.8	20.4	16.7	21.6	13.6	12.4	37.0	19.0	16.7
	Cat ID	2	9	7	8	6	10	11	12	13	14	15	16	17	18	19	20	21

DPC = Days Post Challenge

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1.5	3.4	NS	NS	
2.0	3.5	SN	SN	
5.2	4.5	SN	SN	
5.5	5.4	NS	NS	
5.8	5.6	NS	6.2	
4.2	3.8	5.5	NS	
2.4	1.5	3.2	3.5	
<1.5	<1.5	<1.5	<1.5	
<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

9DPC

8DPC

7DPC

6DPC

SDPC

4DPC

3DPC

2DPC

1DPC

0DPC

Cat ID

CPV Titer From Fecal Material (Log FAID<sub>50</sub>/mg Feces)

Non-Vaccinated Controls

																_		
	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	SN	<1.5	SN	<1.5	<1.5	NS	5.1>	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	SN	<1.5
Vacc	4DPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
	3DPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
	2DPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
	1DPC	<1.5	<1.5	<1.5	<1.5	S.1>	<1.5	5.1>	S.1>	5.1>	5.1>	<1.5	<1.5	<1.5	S.1>	<1.5	5.1>	<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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 $\Box$ 

Study Type	Efficacy
Pertaining to	Canine Parvovirus (CPV)
Study Purpose	To demonstrate effectiveness against CPV
<b>Product Administration</b>	Two doses given at an interval of 28 days were administered
	subcutaneously (SC).
Study Animals	Twenty-five (25) 6-week-old puppies seropositive for parvovirus; 20 vaccinates and 5 non-vaccinated controls.
<b>Challenge Description</b>	Fifty-six days (56) after second vaccination puppies were challenged with CPV type 2c strain.
Interval observed after challenge	Puppies were observed for clinical signs daily for 14 days after challenge
Results	Dogs were determined affected by the criteria of 9 CFR 113.317(c)(3)(i).  Number affected:  Vaccinates: 1/20 (5%) Controls: 4/5 (80%)  See the next page for data.
<b>USDA Approval Date</b>	January 31, 2012

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14DPC 14DPC ğ 13DPC 13DPC 1,3 ğ 12DPC 12DPC ĝ 11DPC 11DPC ĝ 10DPC 10DPC ĝ CPV Post challenge Clinical Observations 9DPC 9DPC Blank - No clinical signs observed ğ 5 SDPC 7DPC 8DPC 2,3,4 2,3 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	84DDV4	(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	4000
ation Titer	d Controls	41DPV1	<2	<2	<2	<2	<2		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	v accinates	(0DPV2)	<2	<2	2	<2	<2	<2	<2	<2	2	<2	2	<2	2	5	<2	<2	<2	<2	<2	ç
		7PV1	4	33	23	10	9		7PV1	80	23	23	23	16	23	4	8	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	cc
		-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	007
		Dog ID	6	1	19	21	27		Dog ID	-	2	3	4	5	9	7	8	10	13	14	15	16	17	18	70	22	23	24	5

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

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10DPC 10DPC 2.13 3.35 2.60 1.98 2.38 2.76 3.28 4.78 1.67 2.33 4.83 2.59 3.30 4.33 1.22 3.54 0.92 g 9DPC 9DPC 2.09 2.11 2.08 3.28 2.52 2.66 1.09 2.24 1.91 2.59 2.83 4.57 3.24 2.59 3.98 2.35 3.34 1.14 2.86 1.27 2.71 20 8DPC 8DPC 1.36 4.18 1.52 2.92 2.42 2.87 2.32 2.51 2.64 3.24 0.93 1.34 3.23 1.44 2.68 1.17 3.01 1.67 2.27 3.61 g 7DPC 7DPC 1.66 2.03 3.23 1.49 2.65 1.53 2.46 1.04 2.04 2.41 0.22 2.23 3.22 4.10 2.90 3.93 0.27 3.27 2.57 1.97 2.51 3.57 6DPC 0.74 69.0 1.59 1.75 1.09 6DPC 3.20 2.34 2.44 3.09 3.66 3.29 3.13 3.04 3.98 1.98 2.70 2.46 2.44 1.81 2.52 2.42 3.31 1.57 Lymphocyte Counts Post Challenge (x10³/µl) 5DPC 5DPC 0.58 0.70 2.75 1.19 2.65 2.35 2.36 1.00 2.73 1.62 1.64 2.98 2.69 3.04 1.29 0.67 2.57 3.07 2.52 4DPC 4DPC 3.75 0.30 0.29 1.42 3.03 1.65 2.03 1.26 1.79 3.28 2.83 2.93 3.05 1.45 1.17 0.92 1.68 2.39 2.85 2.50 2.03 3.01 56 3DPC Vaccinates 3DPC 2.25 1.16 1.78 2.56 3.76 3.35 0.80 1.82 2.42 1.53 3.04 2.62 2.62 2.39 3.38 3.56 2.31 3.27 2.57 1.47 2.91 2.67 2DPC 2DPC 2.26 1.45 2.36 3.05 2.46 2.45 1.55 2.84 2.48 3.18 1.35 2.37 1.32 1.51 1.93 2.43 1.88 3.62 2.08 2.22 2.81 89 1DPC 1DPC 2.28 2.32 2.29 3.23 1.18 2.56 2.42 1.63 2.68 3.32 2.42 1.23 1.84 1.93 2.43 3.10 2.58 3.96 1.81 3.57 2.97 89 Average Average 2.13 1.27 1.86 2.43 2.46 1.67 1.21 1.99 2.94 2.48 2.39 2.09 2.00 3.40 2.42 2.41 0.91 1.92 1.27 ODPC ODPC 1.16 1.18 1.38 2.30 2.34 2.34 2.46 2.66 2.06 2.50 2.05 3.35 2.52 2.00 3.27 2.24 3.02 2.11 1.51 1.87 -1DPC -1DPC 2.14 1.20 2.26 2.50 2.40 1.59 96.0 1.89 2.80 2.25 2.24 2.30 2.54 2.14 2.82 3.05 1.46 2.68 3.06 1.84 1.22 2.04 2.11 -2DPC -2DPC 1.24 2.24 2.68 2.45 2.09 1.10 1.43 2.74 1.26 1.68 2.25 2.06 1.83 0.62 3.80 0.84 1.57 2.07 2.17 2.21 1.67 CatID CatID 18 19 9 13 7 15 16 22 23 24 28 Ξ 21 1 6 S 9 ∞ 27 ব

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

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	10DPC	Na	9.9	<1.5	3.6	<1.5		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	s1.5	s1.5	<1.5	<1.5
	9DPC	Na	9.7≤	4	4.5	≥3.0		9DPC	s1.5	≤1.5	<1.5	s1.5	<1.5	s1.5	s1.5	s1.5	s1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	s1.5	<1.5	<1.5	s1.5
	8DPC	≥9.2	9.8≤	4.2	≤2.8	5.2		8DPC	s1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
200	7DPC	5.2	≥8.5	9.7	6.8	9.9		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	s1.5	<1.5	<1.5	<2.5
	6DPC	7.6	7.5	7.5	6.3	7.4		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	<1.5	<1.5	<1.5
Controls	5DPC 5	9.9	7.2	4.2	4.7	5.2	Vaccinates	5DPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<2.5
Controls	4DPC	<2.5	5.5	2.5	4.3	≤2.8	Vacc	4DPC	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
2	3DPC	s1.5	s1.5	<1.5	≤1.8	<1.5		3DPC	<1.5	<1.5	<1.5	s1.5	<1.5	<1.5	s1.5	<1.5	s1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	s1.5	<1.5	<1.5	<1.5
3	2DPC	s1.5	s1.5	<1.5	<1.5	s1.5		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
	1DPC	s1.5	≥1.8	<1.5	<1.5	<1.5		1DPC	<1.5	s1.8	<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	s1.5	<1.5	<1.5	<1.5
	0DPC	s1.5	s1.5	<1.5	<1.5	s1.5		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	s1.5	<1.5	<1.5	<1.5
	CatID	6	11	19	21	27		CatID	1	2	3	4	5	9	7	8	10	13	14	15	16	17	18	20	22	23	24	28

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Study Type	Safety
Pertaining to	Canine Adenovirus Type-2 (CAV-2)
Study Purpose	Development of corneal opacity is not associated with the use of
	this product
<b>Product Administration</b>	
Study Animals	
<b>Challenge Description</b>	
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.							
<b>Challenge Description</b>	Not applicable							
Interval observed after	No challenge. Observed for 30 minutes after vaccination and							
challenge	then daily for 2 weeks after each vaccination.							
Results	Results are summarized below.							
USDA Approval Date	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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