

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	16E5.23
True Name	Feline Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci Vaccine, Killed Virus, Killed Chlamydia
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Fel-O-Vax IV + CaliciVax - Elanco US Inc.
Date of Compilation Summary	October 13, 2017

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	Feline Calicivirus
Study Purpose	To demonstrate effectiveness against respiratory disease due to
	feline calicivirus
Product Administration	
Study Animals	
Challenge Description	
Interval observed after	
challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance. Study data, however, are no longer available.
USDA Approval Date	April 13, 1990

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Study Type	Efficacy
Pertaining to	Feline Calicivirus (FCV)
Study Purpose	To demonstrate effectiveness against hypervirulent systemic
	(hemorrhagic) form of feline calicivirus disease
Product Administration	Two doses administered subcutaneously three weeks apart.
Study Animals	29 cats, 8 weeks old, randomly divided into 20 vaccinates and 9
	non-vaccinated controls.
Challenge Description	Virulent FCV was administered 14 days after second vaccination
Interval observed after	Cats were observed for clinical signs for 14 days post challenge
challenge	
Results	The primary outcome was the prescence or absence of
	hemorrhagic calicivirus disease. An animal was considered
	affected if any clinical signs of FCV infection were present.
	Positive for clinical FCV:
	Vaccinates: (0/20) (0%) positive
	Controls: 9/9 (100%) positive
	Raw Data for each day postchallenge (DPC):
	Data table is appended to the end of the summary.
USDA Approval Date	February 2, 2005

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					Clir	iical Obsei	Clinical Observations for FCV Challenge	FCV Cha	llenge					
							Vaccinates	,						
9 0 0 0	10PC	2DPC	30PC	4DPC	SDPC	60PC	70PC	8PC	30PC	10DPC	11DPC	12DPC	13DPC	14DPC
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		Deh												
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										Д				
		l Deh								Es				
Г														
		l Deh												
Es - Edema slight														
Deh - Dehydration	_													
	Contraction of the Contraction o													

Blanks=no signs observed

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Dep - Depression/Letharg 1-Left ear skin inflammation SI, Mb,Deh,Py, Ee SS,NB,Deh SS,NB,Deh 14DPC МВ.ру Pylee Dead ď 9 3-Earshot and red 2 - lungs have fluid 5-tip of tail gone SS,NB,Deh, Sl,Mb,Deh, Py,Ee,Rm (ears), Ee SS,B,Deh, hind paws) 4-shaking Py,En (muzzle, 13DPC NB,Py Dead 9 Other -Sl,Deh, Py, SS,NB,Deh, SS,B,py,Em hind paws), (Ears), Ee (Muzzle, Ee, Om 12DPC other Dead ď 9 ω Deh - Dehydration Sn -Sneezing An-Anorexia Al - Alopecia SS,NB, Py, Es Sl,Deh,Py, Ee,Om,Rm SS,Deh,Py, L-Limping Em,Ee, Other⁴ #DPC Dead 9 9 ω (muzzle), Ee SS,Py,Es,Al Deh, Py, Es, OM - Ocular Discharge Mucopurulent RS - Nasal Discharge Serous RM - Nasal Discharge Mucopurulent Mb, Dep, Deh, An, Py, Em NB, Mb, Deh, An, Py, Ee, Al, SS,NB,Deh Deh, An, Es Al, Other (Ears),Om, Other* 100PC PyEs Dead 뜐 9 Mb - Dyspnea Mouth Breathing OS - Ocular Discharge Serous Deh,Py,Em, Al, Other⁴ Dep, Deh, An, Py, Em(muzzle), An, Py, Ee, Rm Deh, An, Es Ee (ears), Dep,Deh, Om, Pin Py,Es,Al MS, NB, Es, OM Clinical Observations for FCV Challenge 90PC Dead Deh, An, Py, An, Py, Ea (hind feet), Es, Other³ Deh, An, Es Dep,Deh,A Ee (muzzle Dep, Deh, Deh,Ea n,Ee, Rm PyEa & Ears) 98 6 å ů Placebo Controls (muzzle), Ee Deh, An, Em Deh, An, Es Dep,Deh,A Deh, An, Py, Deh,An,Es, loss on ears (Ears), Rm some hair ML - Oral Ulcer Multiple Large (>4mm) n,Ee,Rm Ee,Rm MS - Oral Ulcer Multiple Small (<4mm) 70PC ŭ ß ß ŭ NB - External Ulcer Non-Bleeding B - External Ulcer Bleeding PY - Pyoderma Deh,An,Py, L,Em (Ears Deh, An, Em Deh,An,Es, oss on ears Deh, An,Em,Ee Deh,An,L, Ee(muzzle) slight hair Deh, Es (muzzle), Es (Ears), OSor Om paws),Ee Deh, Es (face) 90PC (ears) and ŭ ŭ Deh,Em,Os, Rs Deh,Em,L,S n, Other Dep,Deh Dep, Es Deh,Em Deh, Es Dep, Es SDPC 음 음 Deh, An, Es Dep, Deh, Os, Other¹ Dep, Deh, bloody Dep, Deh 4DPC rectum 음 음 음 EE - Edema Extreme SS - Oral Ulcer Single Small (<4mm) Dep,Deh, An, Al, L SI- Oral Ulcer Single Large (>4mm) 30PC Deh P 9 Per Per Em - Edema Moderate Dep, Al 2DPC Pet Pet Es - Edema slight Cat ID/00PC/10PC N ო ហ Θ _ 4 ۲ω ത

Blanks=no signs observed

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Study Type	Efficacy
Pertaining to	Feline Chlamydia Psittaci (FCP)
Study Purpose	To demonstrate effectiveness against FCP
Product Administration	Two doses administered 21 days apart subcutaneously (SC) or
	Intramuscular (IM).
Study Animals	Thirty (30) cats, 16 to 20 weeks of age. Cats were allocated into
	one vaccinated group of 20 cats, 10 SC and 10 IM, and one
	group of 10 non-vaccinated controls.
Challenge Description	21 days post second vaccination all cats were challenged with
	FCP.
Interval observed after	Rectal temperatures and clinical signs were observed daily for 28
challenge	days post challenge.
Results	Vaccinates and controls were evaluated per the criteria in 9 CFR
	113.71.(3)
	A significant difference in clinical signs was observed between
	vaccinates and controls using a scoring sytem approved by
	APHIS.
	Requirements of 9 CFR 113.71 (3) were met.
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	Raw Data:
	Data tables are appended to the end of the summary.
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USDA Approval Date	April 13, 1990

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		20	103.2	102.0	103.0	103.0	102.2	102.0	102.6	103.0	103.2	102.8	103.4	103.2	102.4	103.2	102.2	102.6	103.8	102.6	102.2	102.6		26	103.6	103.6	103.0	103.0	103.4	103.0	102.0	103.0	102.2	103.0
		27DPC 28DPC	103.3	1018 10	102.4 10	102.6 10	103.0	102.4 10	102.5 10	102.4 10	103.0	102.7 10	104.2 10	102.5 10	102.8 10	103.8 10	1018	102.0	103.0	1018 10	102.4 10	102.0 10		180PC 190PC 200PC 210PC 230PC 240PC 250PC 260PC 270PC 280PC	103.2 10	103.3 10	104.0 10	104.3 10	102.6 10	103.3 10	102.5 10	103.3 10	102.3 10	103.8
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		23DPC 24DPC	3 101.6	9101.6	101.8	102.0	0 101.8	102.4	0 102.2	101.2	0 102.0	2 102.0	6 102.2	101.7	8 102.0	103.4	101.8	102.0	102.4	101.8	101.8	2 102.6		C 24DF	6 103.6	0 104.1	103.0	103.8	103.1	102.8	8 102.8	0 103.6	0 102.6	0 104.0
		C 23DF	101.8	101.6	102.4	102.4	102.0	102.0	102.0	102.0	102.0	102.2	102.6	101.8	102.8	104.0	102.0	101.8	102.4	102.0	102.0	2 102.2		C 23DF	103.6	104.0	103.4	103.4	103.4	102.4	3 102.8	3 103.0	104.0	104.0
		C 22DPC	102.0	101.4	102.0	101.8	101.4	101.8	102.6	1010	102.3	102.1	102.6	101.0	102.4	103.4	101.6	101.4	101.8	101.8	101.6	102.2		C 22DP	102.4	104.4	102.1	103.4	103.2	102.4	103.3	102.8	104.4	101.6
		C 21DPC	102.6	102.2	102.6	102.0	102.2	101.6	102.6	102.0	102.4	103.0	103.0	102.2	102.2	102.8	102.2	102.8	102.0	102.2	102.2	101.8		C 21DP	103.8	103.8	102.6	104.0	102.2	102.6	101.4	103.8	104.0	104.8
		200PC	101.6	101.8	102.7	1022	102.2	102.2	102.6	101.8	102.8	102.6	102.2	102.6	102.8	102.5	101.4	102.0	102.8	102.0	101.6	101.6		20DP(104.8	105.0	103.8	103.2	103.4	103.2	104.6	104.0	103.8	104.5
		19DPC	102.6	101.7	102.5	102.4	102.4	102.2	102.2	101.7	103.2	103.8	103.4	102.2	103.2	102.6	102.4	102.2	103.2	102.1	102.4	102.0		19DPC	105.5	105.2	104.6	103.1	103.4	104.2	104.4	104.2	105.0	104.0
		18DPC	101.6	101.6	102.0	102.4	1022	101.4	101.8	#T0	101.8	102.0	102.0	101.8	102.4	102.6	1022	102.4	101.4	102.4	101.4	101.4		18DPC	104.8	1052	104.8	102.6	103.6	103.0	103.8	104.6	104.6	104.4
lenge		17DPC	102.4	1022	102.8	1022	102.4	103.4	1022	8100	103.0	102.0	102.8	1022	102.8	1022	105.0	104.2	102.8	103.2	1022	101.8		17DPC	104.2	102.4	104.8	103.6	103.4	102.2	103.2	104.4	105.8	102.8
CP Cha		16DPC	102.8	102.4	102.6	102.4	104.0	104.0	102.6	9100	102.6	102.6	102.4	104.4	102.8	102.6	102.2	104.2	102.6	103.4	102.6	101.4		16DPC	105.2	104.4	103.8	103.2	104.2	102.8	103.8	104.0	103.8	104.2
wing F		15DPC	102.4	102.4	102.4	102.2	102.6	101.6	102.6	9100	102.6	102.8	103.2	102.0	102.4	101.4	1018	102.2	103.4	102.6	102.2	102.0	trois	15DPC	104.2	103.2	104.4	102.2	104.2	102.6	102.6	103.8	102.2	105.0
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rature	Vacci	13DPC 14DPC	1020	102.6	102.4	1022	102.0	1022	103.0	101.6	1022	NA	103.0	1018	1024	1018	104.0	1020	103.0	1018	103.2	101.4	/accina	13DPC	104:0	102.8	103.4	102.4	103.8	103.0	102.8	103.2	102.6	104.2
Tempe		12DPC	1026	1013	102.0	103.0	102.6	103.4	1024	020	102.2	103.3	103.2	9101	102.0	101.7	1024	102.2	9101	1024	1018	102.3	N.	12DPC	9000	103.3	103.4	903.6	102.5	101.7	1018	102.8	102.4	1024
Daily Rectal Temperatures Following FCP Challenge			102.0	1018	102.2	102.6	102.0	102.0	102.0	101.8	1018	102.0	103.0	102.4	102.6	1018	101.8	102.8	1024	102.0	102.0	102.0		1DPC /	102.8	102.8	102.6	102.8	102.0	1018	102.0	102.4	102.6	102.2
Daily		10DPC 11DPC	102.8	102.2	102.4	102.6	102.8	102.6	102.4	102.0	102.8	102.6	102.6	102.8	102.6	102.2	103.0	102.4	102.2	102.2	103.0	102.4		10DPC 11DPC 12DPC 13DPC 14DPC 15DPC 16DPC	103.0	102.8	102.6	102.0	102.0	103.2	102.6	102.2	102.4	103.2
		9DPC 1	102.4	1014	102.3	102.6	102.0	102.5	1016	101.4	102.6	102.4	102.0	1018	102.4	1016	102.3	102.2	102.1	1016	102.2	1016		9DPC 1	102.6	102.3	101.7	102.2	1014	102.4	101.6	102.2	1016	103.8
		8DPC 9	102.6	102.0	102.0	102.4	102.4	1016	102.6	101.6	102.0	1014	1016	9101	102.4	1018	102.2	1016	102.8	1014	1018	101.1		8DPC 9	102.0	102.6	102.4	1018	1014	-	102.2	102.4	102.0	1014
		7DPC 8	1016	1016	1018	102.2	102.0	1016	102.4	1016	102.6	102.2	1018	102.8	103.2	102.2	1014	102.0	102.8	102.6	102.6	1014		7DPC 8	102.0	102.4	102.8	1014	1018	102.4	1018	1018	1016	103.4
		6DPC 7	102.4	102.2	102.0	102.4	102.6	102.0	102.8	101.6	102.8	102.6	1018	101.8	102.6	102.4	102.0	102.2	102.4	102.6	102.4	102.0		6DPC 7	102.6	102.4	102.2	102.2	1016	103.0	102.2	102.0	102.2	103.8
		5DPC 6	102.6	101.4	102.6	102.6	101.6	102.6	102.6	101.8	103.0	102.7	102.2	101.4	103.0	101.4	101.4	101.8	102.5	101.8	102.4	101.6		SDPC 6	102.4	101.8	103.0	101.6	102.0	102.4	103.0	103.2	103.0	103.6
		4DPC 5	103.8	102.6	102.6	103.4	102.0	103.6	103.6	102.6	103.6	103.8	103.0	103.0	103.6	102.6	102.4	102.6	103.2	103.8	103.0	103.0		4DPC 51	102.4	102.0	103.6	103.0	102.4	102.4	103.6	103.4	103.0	104.4
		3DPC 4C	102.8 10	101.9	102.5 10	103.2 10	102.3 10	102.4 10	103.2 10	103.2 10	103.5 10	102.7 10	101.8 10	103.0 10	103.4 10	103.0 10	102.8 10	102.6 10	103.1 10	102.5 10	103.1	102.2 10		3DPC 40	102.5 10	102.7 10	103.5 10	102.8 10	102.1 10	103.5 10	103.1 10	103.0 10	102.1 10	104.2 10
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Daily Clinical Signs Following FCP Challenge

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280PC	₹	EIM2	MD	EI/M2	EI/M2		EI/M2	ELM3	ELMS	ELM3				
27DPC	EUNZ	EIMS	EIMS	EWE	27/12	Elws	EUMB	EIMB	Elwis	EIMB				
26DPC	EIMI	EIMS	M2	EIMB	EIMS	ElMS	EIMS	W5	ElMB	EIMB				
250PC	¥	M	М	Et/M2	æ	EI/W3	EI/W3	ELM3	EM3	EI/M2				
24DPC	EUND	EIM	EIM	EUNE	EUNE	ĕ	EUNE	EUMD	ĕ	EUMB				
23DPC	≅	ш	M2	EIMS	EUMI	₩	EIMS	EIMB	EIMS	W2				
220PC		M	M	EIW3	EZMZ	Z	EIW3	EI/WS	EM3	EI/W3				
21DPC			EUNZ	EUNE	EUNZ	ž	EUMD	EUMD	Elwa	EIMD				
20DPC	₹	_	EIMS	Elyes	₹	ElWs	ELLIMO	EIMB	ElMs	EIMB	_	LI O		
190PC	Ξ	×	ELM2	EUM2	EM E	ELM3	E2,M0	ELM3	ELM3	ELM2	I-Depression	k-dehydration		
180PC		¥	EIM2	EfMD		EfWD	EIMD	EIMD	EfWD	DIETMO	_	_		
170PC	≅		EIMS	E)WB	≅	EMB	EIMB	D2,E2,M0	BEUMD	EIMS		pivitis	ş	
160PC			EIMI	EIWB		DQM3	BEIME	DLELJM3	ElWa	EIMB	M1-Slight Conjunctivitis	M2 - moderate Conjunctivitis	M3-Severe Conjunctivitis	
150PC	¥		02E2M3	EI/M2	≅	ElM2	DIETIMS	DLE2JVB	DZEUMB	EZMB	A1-Slight C	M2 - modera	A3-Severe	
14DPC	EIMI		D2,E2,M3	₹	₹	D2,E2,M3	ŽŽ.	ZMI3	-	D2,E3,M3				
130PC	₹	m	DIETMO DRESMO DZEZMO DZEZMO	Ξ		DQE2JMB D2,E2MD	¥	₹	DQE2JMB DQE2MD	DREIJMS DREIJMS DREZSJMS DZESJMI	harge	discharge	charge	
120PC	Z		DIETMO	ω		EZMZ	₹	IM10	DZEUMB	DQED M3	oculardisc	lent ocular	t ocular dis	
11DPC			EIMS			ž	₹	ž	DIEUMS	DQEI M3	copurulent	mucopun e	ncopuruler	
100PC				Ξ		E	Ξ	BM	DLEIJM3	DQETM3	E1 - slight mucopurulent ocular discharge	E2 - Moderate mucopurulent ocular discharge	B - Severe mucopurulent ocular discharge	
90K	¥		M				Ē	Œ	BEIMB	DZETMB				
80 PC				Σ			≅	Σ	EUMB	DIETMB			rdischarge	ar discharge
7DPC	₹			₹			₹	₹	Elws	ElMB			erous ocula	serous ocula
909			M	Ξ			Ξ	Ξ	EUM2	DIEZMO	B-sneezing	C-Cough	D 1-Slight serous ocular discharge	D2 - Severe serous ocular discharge
50PC							₹		EIM	E2JVI3				
흈							₹			₹				
잂	П		П							₹				
띪	\vdash													
Route 10PC 20PC 3DPC 40PC	\vdash	\vdash	Н	\vdash	\vdash	\vdash	\vdash	\vdash	\vdash	\vdash				
쁄														
훈	$oxed{oxed}$	\vdash	\vdash	_	25	9	7		6	10				

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Study Type	Efficacy
Pertaining to	Feline Rhinotracheitis (FVR)
Study Purpose	To demonstrate effectiveness against FVR
Product Administration	
Study Animals	
Challenge Description	
Interval observed after	
challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance. Study data, however, are no longer available.
USDA Approval Date	April 13, 1990

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Study Type	Efficacy
Pertaining to	Feline Panleukopenia Virus (FPV)
Study Purpose	To demonstrate effectiveness against FPV
Product Administration	
Study Animals	
Challenge Description	
Interval observed after	
challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance. Study data, however, are no longer available.
USDA Approval Date	April 13, 1990

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Study Type	Safety												
Pertaining to	All												
Study Purpose	Demonstrate safet	v of produc	t under tv	pical use	conditions								
Product Administratio n	Two doses were a cats 8 weeks of ag	dministered	•			-week ir	ntervals in						
Study Animals	A total of 720 priv	vately owne	ed cats.										
Challenge Description	NA	·											
Interval observed after challenge	Felines were obsetill the second vac following the second	cination. Eand vaccina	ach anima tion and a	l was ther	observed f	or 30 mi	•						
Results	Frequency of Adv	erse Events	S:										
	Post Vaccir	nation React	ion Occurr	ence by do	oses. Total De	oses = 14	16						
	Reaction	≤ 10 Week	old cats	≥ 11 Wee	eks old cats	Total	Doses						
	Category	#	Percent	#	Percent	#	Percent						
	No adverse events	563	96.2%	813	97.8%	1376	97.2%						
	Fever	4	0.7%	0	0%	4	0.3%						
	Lethargy 19 3.2% 16 1.9% 35 2.5% Anorexia 2 0.3% 7 0.8% 9 0.6%												
	Injection Site Swelling	1	0.2%	1	0.1%	2	0.1%						
	Injection Site Pain	4	0.7%	6	0.7%	10	0.7%						
	Vocalization	1	0.2%	2	0.2%	3	0.2%						
USDA	March 24, 2005												
Approval Date	17101011 27, 2003												

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