

## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	15C5.22
True Name	Feline Calicivirus Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Ultra Fel-O-Vax Dual FCV no distributor specified
Date of Compilation Summary	January 24, 2018

## 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.

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

Study Type	Efficacy
Pertaining to	Feline Calicivirus (FCV)
Study Purpose	To demonstrate effectiveness against hypervirulent systemic (hemorrhagic) form of feline calicivirus disease
<b>Product Administration</b>	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
	Pays Data for each day postchallonge (DPC):
	Raw Data for each day postchallenge (DPC):
	Data table is appended to the end of the summary.
USDA Approval Date	February 2, 2005

						Clin	ical Obser	Clinical Observations for FCV Challenge	FCV Cha	llenge					
								Vaccinates							
Cat ID	ODPC	1DPC	2DPC	3DPC	4DPC	SOPC	6DPC	7DPC	8PC	3DPC	10DPC	11DPC	12DPC	13DPC	14DPC
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đ															
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Es - Ede	ma slight														
Deh - De	Deh – Dehydration	c													
Dep - Dé	pression	u'Letharg	2												

Blanks=no signs observed

Placebo Controls       dDeC     SDPC     BPC     BDer, Py, En, AL, Dher, Py, En, Deh, Den, En, B     Deh, Py, En, AL, Dher, Fr, B     Deh, Py, En, AL, Dher, Py, En, Deh, An, Py, Ea     Deh, Py, En, AL, Dher, An, Py, Ea     Deh, Py, En, AL, Dher, An, Py, Ea     Deh, An, Py, Ea       Deh, An, Ex     Deh, An, Py, B     Deh, An, Py, Ea     Deh, An, Py, Ea     Py, Ea, An, Py, Ea     Deh, An, Ph, Ea       Deh, An, Ex     Deh, An, Py, Ea     Deh, An, Py, Ea     Deh, An, Py, Ea     Deh, An, Ph, Ea     Ph, Ea       Deh, An, Ex     Deh, An, Ex     Deh, An, Py, Ea     Deh, An, Py, Ea     Ph, Ea     Ph, Ea       Deh, An, Ex     Deh, An, Ex     Ea, An, Py, Ea     Deh, An, Ph, Ea     Ph, Ea     Deh, An, Ph, Ea     Deh, An, Ph, Ea       Deh, Deh     Deh, Ea     Ea     Deh, An, Ex     Ph, Ea     Ph, Ea     Deh, An, Ea     Deh, An, Ex     Deh, An, Ea     Deh, An	Placebot   ZDPC 3DPC 4DPC SDPC Flacebot   20PC 3DPC 4DPC SDPC 7DPC   20P Deh, Deh, En Deh, An, En Es Es   0s, Other <sup>1</sup> Deh, An, En Es is is in muzzle). En Es in muzzle). En   Dep, Al Deh, An, En Deh, An, Py, Ensish, Rin Deh, An, Py, Es   Deh, Al, L Deh, An, Es Deh, An, En Es, Rin   Deh, Al, L Deh, An, Es Deh, An, En Es, Rin   Deh, Al, L Deh, An, Es Deh, An, En Es, Rin   Deh, Al, L Deh, An, Es Deh, An, En Es, Rin   Deh, Al, L Deh, An, Es Deh, An, En Es, Rin   Deh, An, Es Deh, En Deh, An, En Es, Rin   Deh, An, Es Deh, An, En Es, Rin Es, Rin   Deh, An, Es Deh, An, En Es, Rin Es, Rin   Deh, Deh, Boold Deh, An, En Es (muzzle), Es Es   Deh, Deh, Boold Deh, An, En Es (muzzle), Es Es   NB Deh, Deh, En Deh, An, En Es Es   NB Deh, Deh, En Deh, An, En Es Es   Sigh Es Es Es	Clinical Observations for FCV Challenge	Nations for FUV (	Challenge				
ZDPC     SDPC     SDPC     SDPC     NDPC     NDPC     NDPC     NDDPC     NDDPC<	ZDPC 3DPC 4DPC 5DPC 5DPC 5DPC   Deh, Deh, Deh, B Deh, En, Ds, B Es Es   Dep, Deh, An, E Deh, An, Em, Es Es Es   Dep, Al, L Deh, An, Em, Es Es Es   Dep, Al, L Deh, An, Es Deh, An, Fm Es, An, Py, Is   Dep, Al, L Deh, An, Es Deh, An, Fs Beh, An, Py, Is   Dep, Al, L Deh, An, Es Deh, An, Fs Beh, An, Py, Is   Deh, Al, L Deh, An, Es Deh, An, Es Beh, An, Py, Is   Deh, Al, L Deh, An, Es Deh, An, Es Es, Pm   An, Al, L Deh, An, Es Deh, An, Es Es, Pm   Deh, Deh Deh, En, Es Es, Ran, Is Deh, An, Es   Moderate Deh, En, L, S Deh, An, Es Son An, Es   Moderate Deh, Deh, Deh, Es Es (Ears), In, Es Deh, An, Es   Moderate Deh, Deh, Be, Deh, Be, Deh, Be, Deh, An, Es Son Prair   Moderate Deh, Es Deh, An, Es Son Prair   Moderate Deh, Es Deh, An, Es Son Prair   Moderate Deh, Deh, Be, Deh, Be, Dial Ulcer Multiple Escending Deh, An, Es   Moderate MB - Cotal Ulcer Multiple Escending Deh, An		Placebo Controls					
Image: Section of the sectio	Deh. Deb. Es Es Es Es   Dep. Al Dep. Deh, An, Em, De, An, Em, Es Ears), Rm Deh, An, Fm   Dep. Al Dep. Al, L Deh, An, Em, Es (muzzle), Es   Dep. Al Dep. Al, L Deh, An, Em, Es (muzzle), Es   Dep. Al Deh, An, Fr Deh, An, Fr Deh, An, Fr   Dep. Al Deh, An, Fr Deh, An, Fr Deh, An, Fr   Dep. Al Deh, An, Fr Deh, An, Fr Deh, An, Fr   Dep. Al Deh, An, Fr Deh, An, Fr Es, An, Fr   Deh, An, Fr Deh, An, Fr Deh, An, Fr Es, An, Fr   Deh, An, Fr Deh, An, Er Deh, An, Fr Es, Rm   Deh, An, Er Deh, An, Er Deh, An, Er Es, Rm   Deh, An, Er Deh, An, Er Deh, An, Er Es, Rm   Deh, An, Er Deh, An, Er Deh, An, Er Es, Rm   Deh, Er Deh, Er Deh, An, Er Es, Rm   Deh, Er Deh, Er Deh, An, Er Es   Er Deh, Er Deh, An, Er Es   Er Deh, Er Deh, An, Er Es   Er Deh, Er Deh, An, Er Er   Er Deh, Er Deh, An, Er Er   Er	SDPC			DPC 11DPC	12DPC	13DPC	14DPC
Image: Service of the service of t	Dep, Deh, An, Em, Em, Em, Clash, An, Em, Em, Ee, Rimutzlei). Ee Deh, An, Fin, Riss, Casta). Ee, An, Em, Em, Ea, Sin, An, Em, An, Fin, An, An, An, An, An, An, An, An, An, A	Dep, Es			,Py,Es, SS,NB, Py, Dther <sup>4</sup> Es	, SS,NB,Deh, Py	SS,NB,Deh, Py	SS,NB,Deh, Py
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Image: biolety index inde	Deh Deh Deh, Es Es   Image: Serie state Deh, Serie state Deh, An, Em Deh, An, Em   Image: Serie state Deh, En, L, Serie state Deh, An, L, Serie state Deh, An, L, Serie state   Image: Serie state Deh, Em, L, Serie state Deh, An, L, Serie state Deh, An, L, Serie state Deh, An, L, Serie state   Image: Serie state Deh, Em, L, Serie state Deh, Em, L, Serie state Deh, An, L, Serie state Deh, An, L, Serie state   Image: Serie state Image: Serie state Deh, Em, L, Serie state Deh, An, Es Son ears   Image: Serie state Image: Serie state Image: Serie state Image: Serie state Son of Serie state   Image: Serie state Image: Serie state Image: Serie state Image: Serie state Son of Serie state   Image: Serie state Image: Serie state Image: Serie state Image: Serie state Son of Serie state   Image: Serie state Image: Serie state Image: Serie state Image: Serie state Son of Serie state   Image: Serie state Image: Serie state Image: Serie state Image: Serie state Son of Serie state   Image: Serie state Image: Serie state Image: Serie state Image: Serie state Son of Serie state   Image: Serie state Image: Serie state	Deh,An,Py, L,Em (Ears and paws),Ee (face)			t, Mb, SS,Deh,Py, n, An, Em,Ee, Ee, Al, Other <sup>4</sup>	SS,B,py,Em , (Ears), Ee (Muzzle, hind paws), other <sup>5</sup>	SS,B,Deh, Py, Em (ears), Ee (muzzle, hind paws)	SS,NB,Deh, Py,ee
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NB Deh, Em, L, S Es (Ears), n, Dep, Deh, An, L, n, Ee, Rm Dea, Deh, Am, E, Rm Dead Dead   n, Other <sup>2</sup> Ee (muzzle) n, Ce, Rm n, Ee, Rm Dead Dead   n, Other <sup>2</sup> Ee (muzzle) n, Ee, Rm n, Ee, Rm Dead Dead   n, Other <sup>2</sup> Dep, Deh, Rm Dep, An, Es, Rm n, Ee, Rm Dead Dead   n Dep, Deh, Rm Dep, An, Es, some hair Some hair Deh, An, Es, some hair Deh, An, Es, some hair Deh, An, Es, some hair Deh, An, Es   rectum Deb, Deh, Es Deh, Es Deh, Es Con Am Deh, An, Es Deh, An, Es   Es - Edema slight Deh, Es OS on Om OS on Om Deh, Es Om Deh, Am, Es   En - Edema Moderate MS - Oral Ulcer Multiple Small (K4mm) MS - Oral Ulcer Multiple Large (X4mm) MS - Ocular Discharge Serous   SS - Oral Ulcer Single Small (K4mm) S - Soural Ulcer Rieding MS - Ocular Discharge Serous   SS - Oral Ulcer Single Small (K4mm) S - Soural Discharge Serous	NB Deh, Em, L, S Es (Ears), Es (Ears), n, Other <sup>2</sup> Deh, An, L, Es (Ears), Es (Ears), n, Ee, Pm   NB Deh, Deh, Deh, An, Es, bloody, rectum Deh, An, Es, Beh, An, Es, some hair sight hair loss on ears Deh, An, Es, some hair sight hair loss on ears   Deh, Es Deh, An, Es, Beh, An, Es, some hair sight hair loss on ears Deh, An, Es, some hair sight hair loss on ears   Es Deh, Es Deh, Es   Es Edema slight Deh, Es   Es Edema slight MS - Oral Ulcer Multiple Small (:4mm)   SS - Oral Ulcer Single Small (:4mm) NB - External Ulcer Non-Bleeding	Dep, Es			NB NB	BN	BN	BN
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Deh, Es Deh, Es Deh, Es Om   Deh, Es (muzzle), CS or Om Es Om   Es-Edema slight NS - Oral Ulcer Multiple Small (<4mm)	Deh, Es Deh, Es   Deh, Es Deh, Es   Es - Edema slight CS or Om   Es - Edema slight MS - Oral Ulcer Multiple Small (<4mm)	Dep,Deh Beh,An,Es, slight hair loss on ears			An,Es NB			
MS - Oral Ulcer Multiple Small (<4mm)	MS - Oral Ulcer Multiple Small (<4mm) ML - Oral Ulcer Multiple Large (>4mm) NB - External Ulcer Non-Bleeding B - External Ulcer Bleeding							
ML - Utal Ucer Numpe Large (24mm) UC - Ucuar Uscharge Serous NB - External Ulcer Non-Bleeding OM - Ocular Discharge Mucopurulent BS - Nasel Discharge Serous M - Dr. M - V - Dr. M - V - V - V - V - V - V - V - V - V -	ML - Utal Ucer Mutpe Large (24mm) NB - External Ulcer Non-Bleeding B - External Ulcer Bleeding	MS - Oral Ulcer Multiple Small I		ea Mouth Breathing D: 1 C	Deh - Dehydration	Judration	Other -	
B - External Ulcer Bleeding RS - Nasial Discharge Serous	B - External Ulcer Bleeding	MB - External I licer Non-Blaed	Ē	r Discharge Derous		essionicleman	uep - uepressionicternarg, incert ear skin initammation 1 - Limminn	filuid filuid
		B - External Ulcer Bleeding		Discharge Serous		pri	3 - Ears hot and red	dred
PT = Pyoderma	Pyoderma	PY - Pyoderma	RM - Nasali	Discharge Mucopur		ia	4-shaking	
					An-Anorexia	tia	5 - tip of tail gone	e U

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Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety of product under typical use conditions
Product Administration	A total of 674 cats, 359 eight weeks of age or younger and 315
	greater than 8 weeks, were administered two 0.5mL doses of
	vaccine 3 weeks apart by the subcutaneous route.
Study Animals	Privately owned felines
Challenge Description	NA
Interval observed after	Observed for 30 minutes after first vaccination and then daily for 3
challenge	weeks after first vaccination. Observed for 30 minutes after second
	vaccination and then daily for 2 weeks after second vaccination.
Results	Frequency of events is appended to the end of this summary by
	Veterinary Dictionary for Drug Related Affairs (VeDDRA)
	terminology.
	December 4, 2012
USDA Approval Date	December 4, 2013

## Summary of Reactions:

VeDDRA Code	number ≤62 Days of age	percent ≤62 Days of age	number >62 Days of age	percent >62 Days of age	Total number of cats	Percent of all cats
Normal	241	67.13%	253	80.32%	494	73.29%
Aggression	1	0.28%	1	0.32%	2	0.30%
Injection site Pyoderma	1	0.28%	0	0.00%	1	0.15%
Otitis externa	4	1.11%	3	0.95%	7	1.04%
Hyperactiviy	1	0.28%	1	0.32%	2	0.30%
Injection site self trauma	1	0.28%	2	0.63%	3	0.45%
Abnormal pupil light reflex	1	0.28%	0	0.00%	1	0.15%
Vocalization	1	0.28%	2	0.63%	3	0.45%
Swollen foot	1	0.28%	0	0.00%	1	0.15%
Lymphadenopathy	2	0.56%	0	0.00%	2	0.30%
Ringworm	1	0.28%	0	0.00%	1	0.15%
Death*	24	6.69%	1	0.32%	25	3.71%
No specific sign listed	2	0.56%	2	0.63%	4	0.59%
General Pain	2	0.56%	0	0.00%	2	0.30%
Lameness	1	0.28%	1	0.32%	2	0.30%
Behavioral disorder	1	0.28%	2	0.63%	3	0.45%
Weakness	1	0.28%	0	0.00%	1	0.15%
Injection site swelling (cellulitis)	1	0.28%	0	0.00%	1	0.15%
Depression	14	3.90%	19	6.03%	33	4.90%
Ataxia	1	0.28%	1	0.32%	2	0.30%
Skin abcess	1	0.28%	0	0.00%	1	0.15%
Fever	1	0.28%	9	2.86%	10	1.48%
Tremor	2	0.56%	0	0.00%	2	0.30%
Injection site warmth	1	0.28%	0	0.00%	1	0.15%
Abnormal Breathing	1	0.28%	0	0.00%	1	0.15%
Constipation	1	0.28%	0	0.00%	1	0.15%
Dyspnea	1	0.28%	0	0.00%	1	0.15%
Cardiac murmur	1	0.28%	2	0.63%	3	0.45%
Dental tartar	1	0.28%	0	0.00%	1	0.15%
Corneal edema	1	0.28%	0	0.00%	1	0.15%
Sneezing	48	13.37%	10	3.17%	58	8.61%
Cataract	2	0.56%	0	0.00%	2	0.30%
Blepharospasm	1	0.28%	0	0.00%	1	0.15%
Nasal Discharge	14	3.90%	4	1.27%	18	2.67%
Alopecia at non- injection site area	1	0.28%	1	0.32%	2	0.30%
Ocular discharge	43	11.98%	12	3.81%	55	8.16%

\*Investigator attributed to causes other than vaccination

VeDDRA Code	number ≤62 Days of age	percent ≤62 Days of age	number >62 days of age	percent >62 Days of age	Total number of cats	Percent of all cats
Cough	4	1.11%	1	0.32%	5	0.74%
Dehydration	2	0.56%	0	0.00%	2	0.30%
Conjunctivitis	10	2.79%	5	1.59%	15	2.23%
Not Drinking	6	1.67%	2	0.63%	8	1.19%
Dermatitis or hot spot non-injection site area	2	0.56%	0	0.00%	2	0.30%
Anorexia	6	1.67%	5	1.59%	11	1.63%
Fleas	1	0.28%	0	0.00%	1	0.15%
Decreased appetite	12	3.34%	15	4.76%	27	4.01%
Tapeworms	4	1.11%	0	0.00%	4	0.59%
Lump(s) or bump(s) at non injection site area	1	0.28%	0	0.00%	1	0.15%
Inappropriate urination	1	0.28%	0	0.00%	1	0.15%
Diarrhea	38	10.58%	6	1.90%	44	6.53%
Oral Crustation	1	0.28%	0	0.00%	1	0.15%
Injection site stinging at time of vaccination	6	1.67%	4	1.27%	10	1.48%
Gastroenteritis	12	3.34%	3	0.95%	15	2.23%
Enucleated or swollen eye	2	0.56%	0	0.00%	2	0.30%
Injection Site reaction (<1")**	2	0.56%	0	0.00%	2	0.30%
Loss of condition	8	2.23%	0	0.00%	8	1.19%
Blood in feces	1	0.28%	2	0.63%	3	0.45%
Injection site swelling (1-3")**	1	0.28%	0	0.00%	1	0.15%
Smelly feces	2	0.56%	0	0.00%	2	0.30%
Swollen or kinked tail	1	0.28%	0	0.00%	1	0.15%
Injection site pain	2	0.56%	7	2.22%	9	1.34%
Ear mites	7	1.95%	1	0.32%	8	1.19%

\*\*Injection site swellings were observed for 1 day