

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
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

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
	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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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 ¹ 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				
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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
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					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