



## 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.**

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

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



Clinical Observations for FCV Challenge

Placebo Controls																
Case ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8PC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC	
1					Deh	Dep, Es	Es	Es	Py, Ea	Deh, Py, Em, Al, Other <sup>4</sup>	Deh, Py, Es, Al, Other <sup>4</sup>	SS, NB, Py, Es	SS, NB, Deh, Py	SS, NB, Deh, Py	SS, NB, Deh, Py	
2					Dep, Deh, Os, Other <sup>1</sup>	Dep, Em, Os, Rs	Deh, An, Em, Ee (ears)	Deh, An, Em (muzzle), Ee (Ears), Rm	Deh, An, Py, Ee	Dep, Deh, An, Py, Em (muzzle), Ee (ears), Om, Rm	Mb, Dep, Deh, An, Py, Em (muzzle), Ee (Ears), Om, Rm	SI, Deh, Py, Ee, Om, Rm	SI, Deh, Py, Ee, Om	SI, Mb, Deh, Py, Ee, Rm	SI, Mb, Deh, Py, Ee, Rm	SI, Mb, Deh, Py, Ee
3				Dep, Deh, An, Al, L	Deh, An, Es	Deh, Em	Deh, An, Py, L, Em (Ears and paws), Ee (face)	Deh, An, Py, Ee, Rm	Dep, Deh, An, Py, Ee (hind feet), Ee (muzzle & Ears)	Dep, Deh, An, Py, Ee, Rm	NB, Mb, Deh, An, Py, Ee, Al, Other <sup>4</sup>	SS, Deh, Py, Em, Ee, 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	
4			Deh	Deh	Deh	Deh	Deh, Es	Es	Es, Other <sup>3</sup>	MS, NB, Es, OM	SS, NB, Deh, Py, Es					
5					Deh	Deh	Deh, An, Em	Deh, An, Es	Deh, An, Es	Py, Es, Al	SS, Py, Es, Al	B	B	NB, Py	NB, Py	
6					Dep, Deh	Dep, Es	Es	Es	Es		NB	NB	NB	NB	NB	
7				NB	Deh	Deh, Em, L, S, n, Other <sup>2</sup>	Deh, An, L, Es (Ears), Ee (muzzle)	Dep, Deh, An, Ee, Rm	Dep, Deh, An, Ee, Rm	Dead	Dead	Dead	Dead	Dead	Dead	
8				Deh	Dep, Deh	Dep, Deh	Dep, An, Es, slight hair loss on ears	Dep, An, Es, some hair loss on ears	Deh, Ea	Deh, An, Es	Deh, An, Es	NB				
9						Deh, Es	Deh, Es (muzzle), OS or Om	Es	Om							
							MS - Oral Ulcer Multiple Small (<4mm)	Mb - Dyspnea Mouth Breathing	Deh - Dehydration							
							ML - Oral Ulcer Multiple Large (>4mm)	OS - Ocular Discharge Serous	Dep - Depression/Letharg							
							NB - External Ulcer Non-Bleeding	OM - Ocular Discharge Mucopurulent	L - Limping							
							B - External Ulcer Bleeding	RS - Nasal Discharge Serous	Sn - Sneezing							
							Py - Pyoderma	RM - Nasal Discharge Mucopurulent	Al - Alopecia							
									An - Anorexia							

Blanks=no signs observed

<b>Study Type</b>	Safety
<b>Pertaining to</b>	All
<b>Study Purpose</b>	Demonstrate safety of product under typical use conditions
<b>Product Administration</b>	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.
<b>Study Animals</b>	Privately owned felines
<b>Challenge Description</b>	NA
<b>Interval observed after challenge</b>	Observed for 30 minutes after first vaccination and then daily for 3 weeks after first vaccination. Observed for 30 minutes after second vaccination and then daily for 2 weeks after second vaccination.
<b>Results</b>	Frequency of events is appended to the end of this summary by Veterinary Dictionary for Drug Related Affairs (VeDDRA) terminology.
<b>USDA Approval Date</b>	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%
Hyperactivity	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 abscess	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