



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	16D5.22
True Name	Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Ultra Fel-O-Vax FVRCP - Elanco US Inc.
Date of Compilation Summary	December 26, 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.**

<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

Cat ID	Vaccinates																	
	0DPC	10DPC	20DPC	30DPC	40DPC	50DPC	60DPC	70DPC	8PC	90PC	100PC	110PC	120PC	130PC	14DPC			
1																		
2				Dep. Deh														
3																		
4																		
5																		
6																		
7																		
8			Deh															
9																		
10																		
11			Deh															
12																		
13										P								
14			Deh							Es								
15																		
16																		
17																		
18			Deh															
19																		
20																		
Es - Edema slight																		
Deh - Dehydration																		
Dep - Depression/Lethargy																		

Blanks=no signs observed

Clinical Observations for FCV Challenge																		
Placebo Controls																		
Cat ID	00PC	10PC	20PC	30PC	40PC	50PC	60PC	70PC	8PC	30PC	100PC	110PC	120PC	130PC	140PC			
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 (tears)	Deh, An, Em (muzzle), Ee (Ears), Rm	Deh, An, Py, Ee	Dep, Deh, An, Py, Em (muzzle), Ee (tears), 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, B, Deh, Py, Em (ears), Ee (muzzle, hind paws)	SS, NB, Deh, Py, ee		
4				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	NB, Py		
6					Dep, Deh	Dep, Es	Es	Es	Es		NB	NB	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	Dead	Dead	
8				Deh	Dep, Deh, bloody rectum	Dep, Deh	Dep, An, Es, slight hair loss on ears	Deh, 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									

Blanks=no signs observed

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Feline Rhinotracheitis (FVR)
<b>Study Purpose</b>	To demonstrate effectiveness against FVR
<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 Panleukopenia Virus (FPV)
<b>Study Purpose</b>	To demonstrate effectiveness against FPV
<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>	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%
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