



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	16D5.23
True Name	Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Fel-O-Vax PCT + CaliciVax -- no distributor specified
Date of Compilation Summary	January 29, 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 challenge	Cats were observed for clinical signs for 14 days post challenge
Results	<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>
USDA Approval Date	February 2, 2005

Clinical Observations for FCV Challenge

CatID	Vaccinates																			
	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8PC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC					
1																				
2					Dep. Deh															
3																				
4																				
5																				
6																				
7																				
8				Deh																
9																				
10																				
11					Deh															
12																				
13											P									
14											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																
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 ⁴	Deh, Py, Es, Al, Other ⁴	SS, NB, Py, Es	SS, NB, Deh, Py	SS, NB, Deh, Py	SS, NB, Deh, Py	
2					Dep, Deh, Os, Other ¹	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 ⁴	SS, Deh, Py, Em, Ee, Other ⁴	SS, B, Py, Em (Ears), Ee (Muzzle, hind paws), other ⁵	SS, B, Deh, Py, Em (ears), Ee (muzzle, hind paws)	SS, NB, Deh, Py, ee	SS, NB, Deh, Py, ee
4			Deh	Deh	Deh	Deh	Deh, Es	Es	Es, Other ³	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
7				NB	Deh	Deh, Em, L, Sn, Other ²	Deh, An, L, Es (Ears), Ee (muzzle)	Dep, Deh, An, Ee, Rm	Dep, Deh, An, Ee, Rm	Dead	Dead	Dead	Dead	Dead	Dead	Dead
8				Deh	Dep, Deh	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	NB			
9						Deh, Es	Deh, Es (muzzle), OS or Om	Es	Om							
							MS - Oral Ulcer Multiple Small (<4mm)	Mb - Dyspnea Mouth Breathing	Deh - Dehydration	Other -						
							ML - Oral Ulcer Multiple Large (>4mm)	OS - Ocular Discharge Serous	Dep - Depression/Letharg	1 - Left ear skin inflammation						
							NB - External Ulcer Non-Bleeding	OM - Ocular Discharge Mucopurulent	L - Limping	2 - lungs have fluid						
							B - External Ulcer Bleeding	RS - Nasal Discharge Serous	Sn - Sneezing	3 - Ears hot and red						
							Py - Pyoderma	RM - Nasal Discharge Mucopurulent	Al - Alopecia	4 - shaking						
									An - Anorexia	5 - tip of tail gone						

Blanks=no signs observed

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

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

Study Type	Safety																																																																					
Pertaining to	All																																																																					
Study Purpose	Demonstrate safety of product under typical use conditions																																																																					
Product Administration	Two doses were administered subcutaneously (SC) at 3- to 4-week intervals in cats 8 weeks of age or older.																																																																					
Study Animals	A total of 720 privately owned cats.																																																																					
Challenge Description	NA																																																																					
Interval observed after challenge	Felines were observed for 30 minutes following the first vaccination and daily till the second vaccination. Each animal was then observed for 30 minutes following the second vaccination and again daily for 21 days.																																																																					
Results	<p>Frequency of Adverse Events:</p> <table border="1"> <thead> <tr> <th colspan="7">Post Vaccination Reaction Occurrence by doses. Total Doses = 1416</th> </tr> <tr> <th rowspan="2">Reaction Category</th> <th colspan="2">≤ 10 Week old cats</th> <th colspan="2">≥ 11 Weeks old cats</th> <th colspan="2">Total Doses</th> </tr> <tr> <th>#</th> <th>Percent</th> <th>#</th> <th>Percent</th> <th>#</th> <th>Percent</th> </tr> </thead> <tbody> <tr> <td>No adverse events</td> <td>563</td> <td>96.2%</td> <td>813</td> <td>97.8%</td> <td>1376</td> <td>97.2%</td> </tr> <tr> <td>Fever</td> <td>4</td> <td>0.7%</td> <td>0</td> <td>0%</td> <td>4</td> <td>0.3%</td> </tr> <tr> <td>Lethargy</td> <td>19</td> <td>3.2%</td> <td>16</td> <td>1.9%</td> <td>35</td> <td>2.5%</td> </tr> <tr> <td>Anorexia</td> <td>2</td> <td>0.3%</td> <td>7</td> <td>0.8%</td> <td>9</td> <td>0.6%</td> </tr> <tr> <td>Injection Site Swelling</td> <td>1</td> <td>0.2%</td> <td>1</td> <td>0.1%</td> <td>2</td> <td>0.1%</td> </tr> <tr> <td>Injection Site Pain</td> <td>4</td> <td>0.7%</td> <td>6</td> <td>0.7%</td> <td>10</td> <td>0.7%</td> </tr> <tr> <td>Vocalization</td> <td>1</td> <td>0.2%</td> <td>2</td> <td>0.2%</td> <td>3</td> <td>0.2%</td> </tr> </tbody> </table>	Post Vaccination Reaction Occurrence by doses. Total Doses = 1416							Reaction Category	≤ 10 Week old cats		≥ 11 Weeks old cats		Total Doses		#	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%
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