Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	15B5.21
True Name	Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Fel-O-Vax LvK III + CaliciVax -- 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 challenge	Cats were observed for clinical signs for 14 days post 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 Raw Data for each day postchallenge (DPC): Data table is appended to the end of the summary.
USDA Approval Date	February 2, 2005

Clinical Observations for FCV Challenge

	Vaccinates														
Cat ID	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			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	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]	Deh,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	Sl,Deh,Py, Ee,Om,Rm	Sl,Deh, Py, Ee, Om	Sl,Mb,Deh, Py,Ee,Rm	Sl, Mb,Deh,Py, Ee
3			Dep, Al	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, Ea (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
4			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
6					Dep, Deh	Dep, Es	Es	Es	Es		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
8				Deh	Dep, Deh, bloody rectum	Dep,Deh	Dep, Deh,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						

Es - Edema slight
Em - Edema Moderate
EE - Edema Extreme
SS - Oral Ulcer Single Small (<4mm)
Sl- Oral Ulcer Single Large (>4mm)

MS - Oral Ulcer Multiple Small (<4mm)
ML - Oral Ulcer Multiple Large (>4mm)
NB - External Ulcer Non-Bleeding
B - External Ulcer Bleeding
PY - Pyoderma

Mb - Dyspnea Mouth Breathing
OS - Ocular Discharge Serous
OM - Ocular Discharge Mucopurulent
RS - Nasal Discharge Serous
RM - Nasal Discharge Mucopurulent

Deh - Dehydration
Dep - Depression/Letharg
L - Limping
Sn -Sneezing
Al - Alopecia
An-Anorexia

Other -
1-Left ear skin inflammation
2 - lungs have fluid
3 - Ears hot and red
4-shaking
5 - tip of tail gone

Blanks=no signs observed

Study Type	Efficacy
Pertaining to	Feline Leukemia Virus (FeLV)
Study Purpose	To demonstrate effectiveness against FeLV
Product Administration	Two doses administered 21 days apart subcutaneously (SC) or Intramuscular (IM).
Study Animals	Forty (40) cats 16 to 20 weeks of age. Cats were allocated into one vaccinated group of 20 cats, 10 SC and 10 IM, and one group of 20 non-vaccinated controls.
Challenge Description	14 days post second vaccination all cats were challenged with virulent FeLV.
Interval observed after challenge	All cats were bled once a week for 10 weeks post challenge.
Results	Serum each week was tested for the presence of FeLV (viremia). Animals were considered affected by the challenge if they established a persistent viremia (i.e., tested positive and remained positive). Raw Data: Data tables are appended to the end of the summary.
USDA Approval Date	April 13, 1990

Development of FeLV Viremia in Cats

FeLV Vaccinates

Cat ID	Vaccination Route	0DPC	7DPC	14DPC	21DPC	28DPC	35DPC	45DPC	50DPC	56DPC	63DPC	70DPC
1	IM	-	-	-	-	-	-	-	-	-	-	-
2	IM	-	-	+	+	+	+	+	+	+	+	+
3	IM	-	-	+	-	-	-	-	-	-	-	-
4	IM	-	-	-	-	NA*	NA	NA	NA	NA	NA	NA
5	IM	-	-	+	+	+	+	+	+	+	+	+
6	IM	-	-	-	-	-	-	-	-	-	-	-
7	IM	-	-	-	+	+	+	+	-	-	-	-
8	IM	-	-	+	+	+	+	+	+	+	+	+
9	IM	-	-	-	-	-	-	-	-	-	-	-
10	IM	-	-	+	+	+	-	-	-	-	-	-
11	SC	-	-	-	-	-	-	-	-	-	-	-
12	SC	-	-	+	+	+	+	+	+	+	+	+
13	SC	-	-	-	-	-	-	-	-	-	-	-
14	SC	-	-	-	-	-	-	-	-	-	-	-
15	SC	-	-	+	+	+	+	+	+	+	+	+
16	SC	-	-	-	-	-	-	-	-	-	-	-
17	SC	-	-	-	-	-	-	-	-	-	-	-
18	SC	-	-	-	-	-	-	-	-	-	-	-
19	SC	-	-	-	-	-	-	-	-	-	-	-
20	SC	-	-	-	+	+	+	+	+	+	+	+

Non-Vaccinated Controls

Cat ID	Vaccination Route	0DPC	7DPC	14DPC	21DPC	28DPC	35DPC	45DPC	50DPC	56DPC	63DPC	70DPC
21	NA	-	-	-	+	+	+	+	+	+	+	+
22	NA	-	-	+	+	+	+	+	+	+	+	+
23	NA	-	-	-	+	+	+	+	+	+	+	+
24	NA	-	-	+	+	+	+	+	+	+	+	+
25	NA	-	-	+	+	+	+	+	+	+	+	+
26	NA	-	-	+	+	+	+	+	+	+	+	+
27	NA	-	-	-	-	+	+	-	-	-	-	-
28	NA	-	-	-	+	+	+	+	+	+	+	+
29	NA	-	-	+	+	+	+	+	+	+	+	+
30	NA	-	-	+	+	+	+	+	+	+	+	+
31	NA	-	-	+	+	+	+	+	+	+	+	+
32	NA	-	-	-	-	-	-	-	-	-	-	-
33	NA	-	-	-	-	-	-	-	-	-	-	-
34	NA	-	-	-	+	+	-	-	-	-	-	-
35	NA	-	-	+	+	+	+	+	+	+	+	+
36	NA	-	-	-	+	+	+	+	+	+	+	+
37	NA	-	-	-	+	+	+	+	+	+	+	+
38	NA	-	-	-	+	+	+	+	+	+	+	+
39	NA	-	-	+	+	+	+	+	+	+	+	+
40	NA	-	-	-	+	+	+	+	+	+	+	+

* - Cat found dead (causes not due to FeLV) after sampling on 21DPC

DPC = Days post challenge

NA = Not Applicable

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

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>All</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate safety of product under typical use conditions</td></tr>
<tr><td>Product Administration</td><td>Two doses were administered subcutaneously (SC) at 3- to 4-week intervals in cats 8 weeks of age or older.</td></tr>
<tr><td>Study Animals</td><td>A total of 720 privately owned cats.</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>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.</td></tr>
<tr><td>Results</td><td>Frequency of Adverse Events:

<table>
<tr><th colspan="7">Post Vaccination Reaction Occurrence by doses. Total Doses = 1416</th></tr>
<tr><td rowspan="2">Reaction Category</td><td colspan="2">≤ 10 Week old cats</td><td colspan="2">≥ 11 Weeks old cats</td><td colspan="2">Total Doses</td></tr>
<tr><td>#</td><td>Percent</td><td>#</td><td>Percent</td><td>#</td><td>Percent</td></tr>
<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>
</table>
</td></tr>
<tr><td>USDA Approval Date</td><td>March 24, 2005</td></tr>
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