



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	1555.R5
True Name	Feline Leukemia Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Ultra Fel-O-Vax FeLV -- no distributor specified
Date of Compilation Summary	January 25, 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 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	<p>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).</p> <p>Raw Data: Data tables are appended to the end of the summary.</p>
USDA Approval Date	April 13, 1990

Development of FeLV Viremia in Cats

FeLV Vaccinates

Cat ID	Vaccination Route	ODP C	7DP C	14DP C	21DP C	28DP C	35DPC	45DP C	50DPC	56DPC	63DP C	70DP C
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	ODP C	7DP C	14DP C	21DP C	28DP C	35DPC	45DP C	50DPC	56DPC	63DP C	70DP C
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	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 challenge	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.
Results	Frequency of events is appended to the end of this summary by Veterinary Dictionary for Drug Related Affairs (VeDDRA) terminology.
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%
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