



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	1555.22
True Name	Feline Leukemia Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Felocell FeLV - No distributor specified Vanguard Feline FeLV - No distributor specified
Date of Compilation Summary	June 02, 2021

**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 Leukemia Vaccine (FeLV)						
<b>Study Purpose</b>	To demonstrate efficacy against FeLV in cats.						
<b>Product Administration</b>	Two subcutaneous doses were administered three weeks apart.						
<b>Study Animals</b>	Forty (40) cats, approx. 8 to 10 weeks of age, were randomly assigned into either a placebo control (20 animals) or a vaccinate group (20 animals).						
<b>Challenge Description</b>	Suppressive FeLV challenge was administered two weeks after the second vaccination.						
<b>Interval observed after challenge</b>	Cats were observed for 16 weeks post-challenge. Weekly blood samples were collected throughout this period.						
<b>Results</b>	<p>Cats were defined as persistently viremic if they had three or more positive serum tests for FeLV p27 antigen 12-16 weeks post-challenge.</p> <p><b><u>Table 1: Frequency Distribution of Viremic Cats</u></b></p> <table border="1"> <thead> <tr> <th><b>Treatment Group</b></th> <th><b>No. Affected (%)</b></th> </tr> </thead> <tbody> <tr> <td>Vaccinate</td> <td>4/19 (21%)</td> </tr> <tr> <td>Controls</td> <td>18/20 (90%)</td> </tr> </tbody> </table> <p>Raw data contained on the following pages.</p>	<b>Treatment Group</b>	<b>No. Affected (%)</b>	Vaccinate	4/19 (21%)	Controls	18/20 (90%)
<b>Treatment Group</b>	<b>No. Affected (%)</b>						
Vaccinate	4/19 (21%)						
Controls	18/20 (90%)						
<b>USDA Approval Date</b>	12 March 2008						

**Table 2: Control Treatment Group Results**

Animal ID	Week 3, Day 61		Week 6, Day 83		Week 9, Day 104		Week 12, Day 125		Week 13, Day 132		Week 14, Day 140		Week 15, Day 147		Week 16, Day 154	
	OD	P/WP/N	OD	P/WP/N	OD	P/WP/N	OD	P/WP/N	OD	P/WP/N	OD	P/WP/N	OD	P/WP/N	OD	P/WP/N
T01 06BHT3	1.240	P	0.741	P	0.306	P	0.048	WP	0.348	P	0.056	WP	0.158	P	0.058	WP
T01 06BHU6	0.914	P	0.005	N	-0.005	N	-0.004	N	-0.006	N	-0.004	N	-0.004	N	-0.004	N
T01 06BHZ4	2.780	P	0.651	P	1.021	P	1.332	P	1.555	P	0.696	P	0.851	P	0.851	P
T01 06BIA3	2.772	P	1.265	P	1.422	P	1.624	P	2.341	P	1.688	P	1.285	P	1.388	P
T01 06BIB2	2.164	P	0.063	WP	0.471	P	0.680	P	1.269	P	0.983	P	0.766	P	1.025	P
T01 06JIR2	1.480	P	0.104	WP	0.895	P	1.013	P	1.477	P	0.836	P	0.844	P	1.040	P
T01 06JIS1	2.133	P	0.012	N	-0.003	N	-0.004	N	-0.005	N	-0.003	N	-0.004	N	-0.003	N
T01 06JIT2	2.655	P	1.475	P	2.051	P	1.889	P	2.254	P	1.562	P	1.853	P	1.526	P
T01 06JIU5	3.604	P	3.033	P	1.362	P	3.670	P	3.681	P	2.632	P	2.331	P	2.176	P
T01 06JIV3	1.417	P	0.465	P	0.714	P	1.391	P	1.777	P	1.209	P	0.654	P	0.837	P
T01 06RGW1	3.491	P	2.527	P	2.049	P	1.828	P	2.229	P	1.807	P	1.543	P	1.765	P
T01 06RGX3	2.033	P	2.245	P	1.498	P	1.757	P	1.879	P	1.506	P	0.598	P	1.163	P
T01 06RGZ4	3.450	P	0.988	P	1.771	P	2.297	P	2.321	P	2.209	P	1.642	P	2.525	P
T01 06RGZ5	2.522	P	0.827	P	1.018	P	2.008	P	2.011	P	1.870	P	1.172	P	1.258	P
T01 06RHA2	3.507	P	1.781	P	1.753	P	2.142	P	1.995	P	1.126	P	1.292	P	1.096	P
T01 06RHB3	3.486	P	1.163	P	1.621	P	2.107	P	1.680	P	1.814	P	1.108	P	1.269	P
T01 06RHC4	3.445	P	2.112	P	1.761	P	1.868	P	2.195	P	2.173	P	1.652	P	1.679	P
T01 06RHD3	2.144	P	1.721	P	1.438	P	1.146	P	1.105	P	1.121	P	1.270	P	1.627	P
T01 06RHE1	3.523	P	1.447	P	1.464	P	2.131	P	1.849	P	1.373	P	0.889	P	0.980	P
T01 06RHF2	3.596	P	1.193	P	1.123	P	2.204	P	3.705	P	1.940	P	1.815	P	1.224	P

P/WP/N = Positive, Weak Positive and Negative according to IDEXX (PetCheck, Catalog No. 99-09277) recommendation using the "Screening Protocol"

**Table 3: Vaccinate Treatment Group Results**

Animal ID	Week 3, Day 61		Week 6, Day 83		Week 9, Day 104		Week 12, Day 125		Week 13, Day 132		Week 14, Day 140		Week 15, Day 147		Week 16, Day 154	
	OD	P/WP/N	OD	P/WP/N	OD	P/WP/N	OD	P/WP/N	OD	P/WP/N	OD	P/WP/N	OD	P/WP/N	OD	P/WP/N
T04 06BHT4	-0.004	N	-0.003	N	-0.004	N	-0.004	N	-0.004	N	-0.005	N	-0.005	N	-0.004	N
T04 06BHU7	1.173	P	1.450	P	1.334	P	1.405	P	1.427	P	1.177	P	1.298	P	1.277	P
T04 06BHV3	-0.003	N	-0.002	N	-0.004	N	-0.005	N	-0.004	N	-0.005	N	-0.005	N	0.000	N
T04 06BHW1	1.403	P	0.006	N	-0.004	N	0.007	N	0.020	N	0.016	N	0.004	N	0.007	N
T04 06BHX5	-0.004	N	-0.003	N	-0.004	N	-0.003	N	-0.004	N	-0.004	N	-0.004	N	-0.002	N
T04 06BHY4 <sup>a</sup>	1.065	P	0.103	WP	0.028	N	0.017	N	0.063	WP	0.015	N	0.011	N	0.024	N
T04 06BHZ2	1.194	P	-0.002	N	-0.006	N	-0.005	N	-0.003	N	-0.003	N	-0.004	N	-0.003	N
T04 06BIA2	0.345	P	-0.004	N	-0.005	N	-0.004	N	-0.004	N	-0.003	N	-0.004	N	-0.005	N
T04 06BIB1	0.194	P	0.002	N	-0.004	N	-0.003	N	-0.004	N	-0.003	N	-0.004	N	-0.004	N
T04 06BIC2	0.076	WP	0.001	N	-0.005	N	-0.004	N	-0.005	N	-0.004	N	-0.005	N	-0.003	N
T04 06JIS2	0.260	P	0.000	N	-0.002	N	-0.005	N	-0.004	N	-0.005	N	-0.004	N	-0.004	N
T04 06JIT1	0.364	P	0.026	N	0.013	N	-0.001	N	-0.001	N	-0.003	N	-0.005	N	-0.004	N
T04 06JIU2 <sup>b</sup>	NS	NS	0.085	WP	0.083	WP	D	D	D	D	D	D	D	D	D	D
T04 06JIV1	-0.004	N	-0.002	N	-0.005	N	-0.005	N	-0.004	N	-0.003	N	-0.004	N	-0.005	N
T04 06JIW2	-0.002	N	-0.003	N	-0.005	N	-0.005	N	-0.004	N	-0.005	N	-0.004	N	-0.005	N
T04 06RGW2	2.349	P	1.174	P	1.459	P	1.065	P	1.186	P	0.514	P	0.877	P	0.896	P
T04 06RHB2	3.320	P	1.953	P	2.166	P	1.870	P	2.436	P	1.600	P	1.514	P	2.092	P
T04 06RHC2	-0.003	N	-0.003	N	-0.005	N	-0.004	N	-0.003	N	-0.003	N	-0.005	N	-0.002	N
T04 06RHE2	2.051	P	1.822	P	1.775	P	1.486	P	2.203	P	1.042	P	1.003	P	1.308	P
T04 06RHE5	0.030	N	0.014	N	-0.004	N	-0.005	N	-0.004	N	-0.003	N	-0.003	N	-0.002	N

P/WP/N = Positive, Weak Positive and Negative according to IDEXX (PetCheck, Catalog No. 99-09277) recommendation using the "Screening Protocol"  
D = Deceased

<sup>a</sup>Note that 06BHY4 is weak positive (WP) on week 13 post-challenge probably due to lipemic, hemolysed or icteric sample

<sup>b</sup>Cause of Death = Heart failure (non FeLV-related)

<b>Study Type</b>	Safety																																																																																											
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<b>Study Purpose</b>	To demonstrate safety of product in typical field conditions.																																																																																											
<b>Product Administration</b>	Two doses administered subcutaneously, 3-4 weeks apart.																																																																																											
<b>Study Animals</b>	143 minimum age cats (8-9 weeks-old) were vaccinated																																																																																											
<b>Challenge Description</b>	N/A																																																																																											
<b>Interval observed</b>	Immediate vaccination reactions were documented for 30 minutes following each vaccination, and late post-vaccination reactions were documented for 14 days following each vaccination.																																																																																											
<b>Results</b>	<p>Reduced-scale field safety study to support manufacturing change that reduces adverse events.</p> <p><b><u>Table 1: Frequency Distribution of Immediate Post-vaccination Reactions Observed</u></b></p> <table border="1"> <thead> <tr> <th>Clinical signs</th> <th>Vaccination</th> <th>Number of events</th> <th>Total injections</th> <th>Events in total<sup>1</sup> (%)</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Vocalization</td> <td>First</td> <td>1</td> <td>143</td> <td>3/278</td> </tr> <tr> <td>Second</td> <td>2</td> <td>135</td> <td>(1.1%)</td> </tr> <tr> <td rowspan="2">Injection site stinging</td> <td>First</td> <td>2</td> <td>143</td> <td>3/278</td> </tr> <tr> <td>Second</td> <td>1</td> <td>135</td> <td>(1.1%)</td> </tr> </tbody> </table> <p><sup>1</sup>: Total of first (143) and second (135) vaccinations = 278 injections</p> <p><b><u>Table 2: Late Post-vaccination Reactions Observed</u></b></p> <table border="1"> <thead> <tr> <th>Clinical signs</th> <th>Vaccination</th> <th>Number of events</th> <th>Total injections</th> <th>Events in total<sup>2</sup> (%)</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Anorexia</td> <td>First</td> <td>4</td> <td>143</td> <td>4/279</td> </tr> <tr> <td>Second</td> <td>0</td> <td>136</td> <td>(1.4%)</td> </tr> <tr> <td rowspan="2">Behavior change</td> <td>First</td> <td>2</td> <td>143</td> <td>2/279</td> </tr> <tr> <td>Second</td> <td>0</td> <td>136</td> <td>(0.7%)</td> </tr> <tr> <td rowspan="2">Decreased Appetite</td> <td>First</td> <td>1</td> <td>143</td> <td>1/279</td> </tr> <tr> <td>Second</td> <td>0</td> <td>136</td> <td>(0.4%)</td> </tr> <tr> <td rowspan="2">Depression &amp; Lethargy</td> <td>First</td> <td>3</td> <td>143</td> <td>3/279</td> </tr> <tr> <td>Second</td> <td>0</td> <td>136</td> <td>(1.1%)</td> </tr> <tr> <td rowspan="2">Injection site pain</td> <td>First</td> <td>4</td> <td>143</td> <td>4/279</td> </tr> <tr> <td>Second</td> <td>0</td> <td>136</td> <td>(1.4%)</td> </tr> <tr> <td rowspan="2">Lameness</td> <td>First</td> <td>2</td> <td>143</td> <td>2/279</td> </tr> <tr> <td>Second</td> <td>0</td> <td>136</td> <td>(0.7%)</td> </tr> <tr> <td rowspan="2">Hard injection site swelling</td> <td>First</td> <td>0</td> <td>143</td> <td>4/279</td> </tr> <tr> <td>Second</td> <td>4</td> <td>136</td> <td>(1.4%)</td> </tr> </tbody> </table> <p><sup>2</sup>: Total of first (143) and second (136) vaccinations = 279 injections</p>	Clinical signs	Vaccination	Number of events	Total injections	Events in total <sup>1</sup> (%)	Vocalization	First	1	143	3/278	Second	2	135	(1.1%)	Injection site stinging	First	2	143	3/278	Second	1	135	(1.1%)	Clinical signs	Vaccination	Number of events	Total injections	Events in total <sup>2</sup> (%)	Anorexia	First	4	143	4/279	Second	0	136	(1.4%)	Behavior change	First	2	143	2/279	Second	0	136	(0.7%)	Decreased Appetite	First	1	143	1/279	Second	0	136	(0.4%)	Depression & Lethargy	First	3	143	3/279	Second	0	136	(1.1%)	Injection site pain	First	4	143	4/279	Second	0	136	(1.4%)	Lameness	First	2	143	2/279	Second	0	136	(0.7%)	Hard injection site swelling	First	0	143	4/279	Second	4	136	(1.4%)
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<b>USDA Approval Date</b>	29 January 2015																																																																																											

<b>Study Type</b>	Safety
<b>Pertaining to</b>	All
<b>Study Purpose</b>	To demonstrate safety under typical field conditions.
<b>Product Administration</b>	Two doses administered subcutaneously, 3-4 weeks apart.
<b>Study Animals</b>	A total of 621 were vaccinated in 11 veterinary clinics in 3 different geographic locations. One hundred ninety-two cats were 8-9 weeks old (minimum age) and 429 cats were 10 weeks of age or older.
<b>Challenge Description</b>	N/A
<b>Interval observed</b>	Cats were monitored for 1 hour at the clinic and 14 days post-vaccination.
<b>Results</b>	Please see raw data below.
<b>USDA Approval Date</b>	October 16, 2009

**Table 1: Frequency Distribution of Immediate Post-vaccination Reactions Observed Associated with Vaccinations**

<b>Clinical signs</b>	<b>Vaccination</b>	<b>Number of events</b>	<b>Total injections</b>	<b>Events in total<sup>1</sup> (%)</b>
Vocalization	First	195	636	292/956 (30.5%)
	Second	97	320	
Injection site stinging	First	126	636	185/956 (19.4%)
	Second	59	320	
Injection Site Self Trauma	First	5	636	6/956 (0.6%)
	Second	1	320	
Lameness	First	3	636	3/956 (0.3%)
	Second	0	320	

<sup>1</sup>Total of first (636) and second (320) vaccinations = 956 injections

**Table 2: Late Post-vaccination Reactions Observed Associated with Vaccinations**

<b>Clinical signs</b>	<b>Vaccination</b>	<b>Number of events</b>	<b>Total injections</b>	<b>Events in total<sup>2</sup> (%)</b>
Depression	First	27	636	31/956 (3.2%)
	Second	4	320	
Injection Site Pain	First	15	636	18/956 (1.9%)
	Second	3	320	
Decreased Appetite	First	9	636	9/956 (0.9%)
	Second	0	320	
Lameness	First	8	636	11/956 (1.2%)
	Second	3	320	
Anorexia	First	6	636	6/956 (0.6%)
	Second	0	320	
Hyperthermia	First	3	636	4/956 (0.4%)
	Second	1	320	
Vomiting	First	3	636	3/956 (0.3%)
	Second	0	320	
Injection Site Swelling	First	2	636	3/956 (0.3%)
	Second	1	320	
Not Drinking	First	2	636	2/956 (0.2%)
	Second	0	320	
Behavioral Disorder	First	1	636	1/956 (0.1%)
	Second	0	320	
Diarrhea	First	1	636	2/956 (0.2%)
	Second	1	320	
Muscle Pain	First	1	636	1/956 (0.1%)
	Second	0	320	

<sup>2</sup>: Total of first (636) and second (320) vaccinations = 956 injections