



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	1559.2C
True Name	Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci Vaccine, Modified Live & Killed Virus, Killed Chlamydia
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Fel-O-Guard Plus 4 + Lv-K -- Elanco US, Inc.
Date of Compilation Summary	December 19, 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.

Study Type	Efficacy
Pertaining to	Feline Calicivirus (FCV)
Study Purpose	To demonstrate effectiveness against respiratory disease due to Feline Calicivirus
Product Administration	Two doses administered 21 days apart subcutaneously (SC)
Study Animals	Thirty three (33) cats, 8 weeks of age. Cat were randomized into one vaccinated group of 23 cats and one group of 10 non-vaccinated controls.
Challenge Description	31 days post second vaccination all cats were challenged with FCV.
Interval observed after challenge	Rectal temperatures and clinical signs were observed daily for 14 days post challenge.
Results	<p>Vaccinates and controls were evaluated per the criteria in 9 CFR 113.314.(c)(3)</p> <p>A significant difference in clinical signs was observed between vaccinates and controls using a scoring sytem approved by APHIS.</p> <p>Requirements of 113.314.(c)(3) were met.</p> <p>Raw Data: Data tables are appended to the end of the summary.</p>
USDA Approval Date	November 4, 1998

FCV Post challenge Daily Clinical Signs

Vaccinates															
Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1					1	2	2	2	2	2	2	2	2	2	2
2					2	2	2	2	2	2	2	2	2	2	2
3						1	1	1	1	1					
4				3	2	2	2	2	2	2	2	2	2	2	2
5															
6															
7				2	2	2	2	2	2	2	2	2	2	1	1
8							1	1							
9									1	1	1	1	1	1	1
10						3,2	3,2	3,2	3,2	3,2	3	3	3	1	
11					1,2,5	1,2,5	1,2,5	1,2,5	1,2,5	1,2,5	2,5	2,5	1,5	1	1
12															
13					1	1	1	1	1	1	1	1	1	1	1
14					5				3,6	1					
15						1	1	1	1	1	1	1	1	1	1
16				2	2	2	2	2	2	2	2	2	2	2	2
17				1	1	2	2	2	2	2	2	2	2	2	2
18				2	2	2	2	2	2	2	2	2	2	2	2
19					1	2	2	2	2	2	2	2	2	2	1
20															
21															
22				5	5	5	5								
23					2	1,2	1,2	1,2	1,2	1,2	2	2	1	1	1

- 1- One oral ulcer <4mm
- 2- One oral ulcer >4mm
- 3- Multiple oral ulcers <4mm
- 4- Multiple oral ulcers >4mm

- 5- External Non-bleeding ulcer(s)
- 6- External bleeding ulcer(s)
- 7- Anorexia
- 8- Dehydration

- 9 - snuffing
- 10 - coughing
- 11- mouth breathing
- 12 - Depression

No entry=no signs noted

DPC=days post challenge

FCV Post challenge Daily Clinical Signs

Non-Vaccinated Controls															
Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1							5	5	5	5	5				
2				1	1	1,2,6	1,2,6	1,2,6	2,6	2,6	2,6	2,6	2,6	2,6	2,6
3					2	4	4	4	4	4	3				
4				1	2	2	2	1,2	1,2	1,2	1,2	3,2	3,2	3,2	2
5				2	2	2	2	2	2	2	2	2	2	2	2
6				3,2	2	2	2	2	2	2	2	2	2	2	2
7										1	1	1	1	1	1
8						4,6	4,6	4,6	4,6	4,6	4,6	4,6	1,2,5	1,2,5	1,2,5
9					2	2	2	1,2	1,2	1,2	2	2	2	2	2
10						3	3	4	4	4	4	1,2	1,2	1,2	3

1- One oral ulcer <4mm

2- One oral ulcer >4mm

3- Multiple oral ulcers <4mm

4- Multiple oral ulcers >4mm

5- External Non-bleeding ulcer(s)

6- External bleeding ulcer(s)

7- Anorexia

8- Dehydration

9 - snuffing

10 - coughing

11- mouth breathing

12 - Depression

No entry=no signs noted

DPC=days post challenge

FCV Post challenge Daily Body Temperature (°F)

Vaccinates															
Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1	101.9	102.4	101.9	102.2	102.1	102.4	101.3	101.4	101.6	101.5	101.2	101.1	101.1	101.1	101.3
2	101.7	101.6	101.9	102.1	103.1	101.4	101.8	101.0	101.8	101.4	101.7	101.4	101.7	101.3	101.8
3	101.2	102.1	101.8	102.7	101.5	101.8	101.2	101.0	101.4	101.1	101.0	101.1	101.4	101.0	101.7
4	101.8	102.6	101.7	102.6	101.9	102.0	102.0	101.5	101.2	101.8	101.7	101.7	101.2	101.8	101.7
5	100.8	101.0	100.8	101.6	101.5	101.4	101.4	101.9	101.7	101.5	101.1	101.3	101.1	101.4	101.4
6	101.7	102.1	101.3	101.1	101.3	101.1	101.5	101.0	101.4	101.7	101.2	101.5	101.0	101.2	101.6
7	101.2	103.2	101.5	102.6	101.9	101.5	101.5	101.0	101.5	101.4	101.9	101.9	101.9	101.3	101.9
8	101.6	101.7	101.6	101.9	101.7	101.9	101.5	101.7	101.5	101.5	101.5	101.6	101.2	101.5	101.0
9	101.5	102.1	101.7	101.9	102.0	101.8	101.2	101.6	101.6	101.1	101.8	101.6	101.7	101.1	101.1
10	101.3	103.1	102.1	102.1	102.1	101.7	101.8	101.0	101.4	101.4	101.4	101.5	101.1	101.0	101.8
11	100.3	102.2	102.1	103.0	102.9	102.1	102.0	101.0	101.5	101.6	101.9	101.4	101.0	101.0	101.2
12	102.3	103.0	102.4	101.6	101.7	103.1	101.8	102.2	101.8	101.4	101.7	101.9	101.9	101.3	101.1
13	101.2	101.4	101.2	101.7	101.2	101.8	101.7	101.4	101.8	101.1	101.4	101.4	101.5	101.4	101.5
14	100.4	102.3	101.8	101.2	101.7	101.9	101.5	101.3	101.8	101.9	101.1	101.1	101.7	101.6	101.5
15	101.6	102.1	102.4	102.0	101.6	101.6	101.2	101.2	102.3	101.5	101.2	101.0	101.6	101.0	101.0
16	100.9	102.1	103.7	103.4	102.9	102.5	102.3	101.8	101.4	101.6	101.3	101.2	101.2	101.0	101.1
17	101.5	102.8	101.8	102.4	102.6	102.1	101.1	101.8	101.6	101.9	102.0	101.9	101.4	101.4	102.0
18	101.0	102.0	101.1	103.4		101.1	101.0	101.0	101.1	101.2	101.2	101.3	101.7	101.3	101.6
19	100.8	102.5	101.4	101.0	102.1	101.5	101.8	101.3	101.1	101.8	101.4	101.4	101.3	101.1	101.0
20	100.5	101.7	101.7	101.4	102.0	101.0	101.6	101.3	101.2	101.1	101.1	101.4	101.7	101.1	101.0
21	101.9	102.4	102.0	101.8	101.8	101.9	101.1	101.5	101.8	101.8	102.0	102.1	101.1	101.2	101.6
22	100.4	101.7	102.1	102.0	102.0	101.2	101.6	101.4	102.0	101.3	101.9	101.4	101.1	101.1	101.0
23	101.0	102.7	102.6	102.8	101.4	102.3	101.6	101.3	101.4	101.0	101.3	101.6	101.5	101.6	101.2

DPC=days post challenge

FCV Post challenge Daily Body Temperature (°F)

Non-Vaccinated Controls															
Cat ID	0DP C	1DP C	2DP C	3DP C	4DP C	5DP C	6DP C	7DP C	8DP C	9DP C	10DP C	11DP C	12DP C	13DP C	14DP C
1	100.3	102.1	101.7	101.5	102.1	102.4	102.4	101.7	102.0	101.0	101.4	101.0	101.0	101.6	101.3
2	101.0	101.7	101.4	102.2	102.9	102.1	101.6	101.3	101.5	101.3	101.1	101.4	101.4	101.5	101.1
3	102.0	102.8	101.9	102.3	101.8	101.3	101.2	101.3	101.4	101.7	101.9	101.4	101.0	101.6	101.2
4	102.7	102.7	102.4	102.8	102.8	101.5	101.2	101.8	101.3	101.2	101.1	101.7	101.6	101.2	101.4
5	101.7	102.1	102.1	103.6	102.3	102.7	102.1	102.2	102.0	101.1	101.2	101.1	101.6	101.0	101.7
6	101.0	102.0	101.4	104.0	103.0	103.1	102.7	101.0	101.0	101.3	101.0	101.0	101.0	101.3	101.7
7	101.1	102.6	101.3	101.4	102.0	102.3	101.4	101.3	101.1	101.6	101.5	101.6	101.8	101.9	101.2
8	102.0	102.5	102.1	101.6	101.1	102.4	101.6	101.7	101.7	102.1	101.2	101.5	101.6	101.3	101.6
9	102.1	102.2	102.0	102.4	103.2	103.2	102.1	102.3	101.6	101.6	101.5	101.7	101.2	101.1	101.0
10	102.7	102.4	103.7	104.6	103.9	102.9	101.3	102.5	101.9	101.8	101.7	101.1	101.2	101.2	101.3

DPC=days post challenge

Study Type	Efficacy
Pertaining to	Feline Chlamydia Psittaci (FCP)
Study Purpose	To demonstrate effectiveness against FCP
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	November 4, 1998

Study Type	Efficacy
Pertaining to	Feline Leukemia Virus (FeLV)
Study Purpose	To demonstrate effectiveness against FeLV
Product Administration	Two doses administered 4 weeks apart subcutaneously (SC)
Study Animals	Thirty-three (33) eight week old cats. Cats were randomized into one vaccinated group of 24 cats and one group of 9 non-vaccinated controls.
Challenge Description	4 weeks post second vaccination all cats were challenged with virulent FeLV.
Interval observed after challenge	All cats were monitored and bled once a week for 12 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 (positive on 3 or more consecutive bleedings).</p> <p>Raw Data: Data tables are appended to the end of the summary.</p>
USDA Approval Date	June 28, 1999

Development of FeLV Viremia in Cats

FeLV Vaccinates

Cat ID	0DP C	7DP C	14DP C	21DP C	28DP C	35DP C	42DP C	49DP C	56DP C	63DP C	70DP C	77DP C	84DP C
1	-	-	-	-	-	-	-	-	-	-	-	-	-
2	-	-	-	-	+	+	+	+	+	+	+	+	+
3	-	-	-	+	+	+	+	+	+	+	+	+	+
4	-	-	-	-	-	-	-	-	-	-	-	-	-
5	-	-	-	+	+	+	+	+	+	+	+	+	+
6	-	-	-	-	-	-	-	-	-	-	-	-	-
7	-	-	-	-	-	-	-	-	-	-	-	-	-
8	-	-	-	+	+	+	+	+	+	+	+	+	+
9	-	-	-	-	-	-	-	-	-	-	-	-	-
10	-	-	-	+	+	+	+	+	+	+	+	+	+
11	-	-	-	-	+	+	+	+	+	+	+	+	+
12	-	-	-	-	-	-	-	-	-	-	-	-	-
13	-	-	-	-	-	-	-	-	+	+	-	-	-
14	-	-	-	+	+	+	+	+	+	+	+	+	+
15	-	-	-	-	-	-	-	-	-	-	-	-	-
16	-	-	-	-	-	-	-	-	-	-	-	-	-
17	-	-	-	-	-	-	-	+	+	+	+	+	+
18	-	-	-	-	-	-	-	-	+	+	+	-	+
19	-	-	-	-	-	-	-	-	-	-	-	-	-
20	-	-	-	-	-	-	-	-	-	-	-	-	-
21	-	-	-	-	-	+	+	+	+	+	+	+	+
22	-	-	-	-	-	-	-	-	-	-	-	-	-
23	-	-	-	-	+	+	-	-	-	-	-	-	-
24	-	-	-	-	-	-	-	-	-	-	-	-	-

Non-Vaccinated Controls

Cat ID	0DP C	7DP C	14DP C	21DP C	28DP C	35DP C	45DP C	50DP C	56DP C	63DP C	70DP C	77DP C	84DP C
1	-	-	-	+	+	+	+	+	+	+	+	+	+
2	-	-	+	+	+	+	+	+	+	+	+	+	+
3	-	-	-	+	+	+	+	+	+	+	+	+	+
4	-	-	+	+	+	+	+	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	-	-	-	-	-
6	-	-	-	+	+	+	+	+	+	+	+	+	+
7	-	-	+	+	+	+	+	+	+	+	+	+	+
8	-	-	-	+	+	+	+	+	+	+	+	+	+
9	-	-	-	+	+	+	+	+	+	+	+	+	+

DPC = Days Post Challenge
 + = positive for FeLV Viremia
 - = negative for FeLV Viremia

Study Type	Efficacy
Pertaining to	Feline Viral Rhinotracheitis (FVR)
Study Purpose	To demonstrate effectiveness against FVR
Product Administration	Two doses administered 21 days apart subcutaneously (SC)
Study Animals	Forty-two (42) cats, 8 weeks of age. Cats were randomized into two vaccinated groups of 22 and 10 cats, respectively, and one group of 10 non-vaccinated controls.
Challenge Description	21 days post second vaccination all cats were challenged with FVR virus.
Interval observed after challenge	Rectal temperatures and clinical signs were observed daily for 14 days post challenge.
Results	<p>Vaccinates and controls were evaluated per the criteria in 9 CFR 113.315(c)(3).</p> <p>A significant difference in clinical signs was observed between vaccinates and controls using a scoring system approved by APHIS.</p> <p>Requirements of 113.315.(3) were met.</p> <p>Raw Data: Data tables are appended to the end of the summary.</p>
USDA Approval Date	July 1, 1999

FVR Post challenge Daily Clinical Signs

Vaccinates - : Group 1															
Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1				SN	D, DH, DY	DH, NSM, AN	SN, DH, AN	SN, NSM, AN	SN, AN	NSM, AN	SN, OSM, NSM, AN	OSM, NSM, AN	NSM, AN	SN	AN
2		D		D	OSM, NSM	D, DH, NSM	SN, DH, AN	OSM, NSM, AN	OMM, MMM, AN	OSM, NMM, AN	NSM, AN	NSM, AN		NSM	MMM
3						OSM		OSM, NSM	OSM, NSM	NSM	NSM	NSM			NSM
4							SN	SN, NSM	NSM	SN, NSM	NSM	SN, NSM	SN, NSM	SN, NSM	NSM
5							OSM	OSM	OSM			OSM, NSM	OSM, NSM	SN, NSM	
6					SN	DH		NSM		SN				NSM	
7				SN		SN, OSM		SN, OSM	NSM		SN	NSM	SN, NSM	SN	
8					SN, DY		SN, DY	SN	AN	SN, NSM	NSM	NSM	NSM		NSM
9							SN	SN, OSM, NSM	AN	NSM, AN		NSM	NSM	NSM	NSM
10							OSM	OSM	OSM, NSM	SN, OSM	OSM, MMM	NSM			
11					OSM	OSM, NSM	DY	SN	NSM	NSM	NSM	NSM	NSM	SN, NSM	MMM
12				SN		OSM	OSM	SN, OSM	NSM		NSM	NSM	OSM		
13								NSM							
14								SN							
15							OSM	OSM	NSM	SN	NSM	NSM		SN	
16				SN	SN	SN, OSM	SN, DY	SN, NSM			SN, NSM	NSM	SN, OMM, NSM	SN	
17					SN	AN	AN	SN, NSM, AN	AN						
18								NSM	SN, NSM	NSM	SN	NSM	NSM		NSM
19							SN			NSM	NSM			SN	
20						AN	AN	SN, OSM, NSM, AN	AN	NSM, AN	NSM, AN	NSM	NSM	SN	NSM
21					SN, AN	SN, DH, AN	SN, OSM, AN	OSM, NSM, AN	OSM, NMM, AN	SN, DH, OSM, NSM, AN	SN, OSD, NSD, AN	SN, OMM, NMM, AN	SN, OMM, NMM, AN	SN, NSM, AN	NSM, AN
22								SN, NSM, AN	NSM, AN	AN	NSM, AN	NSM			

Empty=no signs observed

Ocular Discharge	Nasal Discharge	SN-Sneezing	CO-Coughing
OSM-Mild serous	NSM - Mild Serous	AN-Anorexia	BR-Open Mouth Breathing
OSD-Moderate serous	NSD-Moderate Serous	DH-Dehydration	D-Depression
OMM-Mild Mucoid	NMM-Mild Mucoid	DY-Snuffing	
OMD-Moderate Mucoid	NMD-Moderate Mucoid		

FVR Post challenge Daily Clinical Signs

Vaccinates - Group 2

Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1					SN			NSM	SN,NSM	NMM	AN	NSM	SN,NSM	SN,NSM	
2			SN	SN,CO,OSM	SN,OSM,BR	SN,OSM	SN,OSM	SN,OSM,NSM	SN,OSM,NSM	SN,OSM,NSM	SN,OSM	OSM	SN,OSM		
3					OSM	OSM	OSM	OSM	SN,NSM	SN,OSM,NSM	NSM	OSM,NSM		NSM	
4					OSM	OSM	OSM	SN,NSM		SN,NSM	NSM			SN	NMM
5					OSM	OSM	NSM	SN	SN,NSM	NSM,AN	SN,OSM	OSM	SN,OSM	SN	
6					SN,OSM			SN,NSM	NSM	NSM	SN,OSM	SN	NSM	SN	
7				D											
8			SN	SN,OSM	AN	SN	SN,AN	NSM,AN	OSM,NSM,AN	NMM,AN	NMM,AN	NMM,AN		SN	AN
9			SN	SN,OSM	SN,OSM	SN	SN,OSM,NSM	NSM	NSM	SN	SN,OSM	SN	SN,NSM	SN	
10					DY,OSM			SN,OSM,NSM,AN	OSM,NMM,AN	SN,NMM	OSM,NSM	NSM	NSM	SN,NSM	NSM

Non-Vaccinated Controls

Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1						SN,D,OSM	SN	SN,OSM,NSM	NSM	SN,NSM		SN,NSM	NSM		
2					OSM	OSM	SN,AN	SN,NSM,AN	OSM,AN	DH,OMM,NMM,AN	SN,OMM,NMM,AN	OMM,NMM,AN	OMM,NMM,AN	SN,OMM,NMM,AN	NSM,AN
3					SN	DH,OSM		NSM,AN	SN,D,DY,OSM,AN	SN,OSM,NSM,AN	OMM,AN	OMM,AN	OSM,AN	SN	AN
4					OSM	OSM	OSM	OSM	OSM,NSM,AN	SN,OSM,AN	OSM	OSM	NSM		
5		AN			SN,OSM,AN	SN,OSM,AN	OSM	SN,OSM,NSM	NSM,AN	NSM,AN	SN,AN	NSM,AN	NSM,AN	SN,NSM,AN	NSM,AN
6			SN		SN,OSM	SN,OSM	SN	SN	SN,NSM	NSM	SN,NSM		SN,NSM	SN,NSM	
7			SN		SN	SN,OSM	SN,OSM	SN,AN	SN,OSM,AN	SN,NSM,AN	SN,AN	SN	SN		
8			SN		SN,NSM			SN	DY,NSM	SN,OSM			SN	NSM	
9								SN,OSM	NSM	OSM	SN,NSM	NSM	NSM	SN,NSM	
10					SN,DY	SN,OSM,BR,AN	SN,OSM,AN	SN,OSM,NSM,AN	DY,OSM,NSM,AN	SN,OSM,NSM,AN	OSM,NSM,AN	OSM,NSM,AN	SN	SN	AN

Ocular Discharge	Nasal Discharge	SN-Sneezing	CO-Coughing
OSM-Mild serous	NSM - Mild Serous	AN-Anorexia	BR-Open Mouth Breathing
OSD-Moderate serous	NSD-Moderate Serous	DH-Dehydration	D-Depression
OMM-Mild Mucoid	NMM-Mild Mucoid	DY-Snuffing	
OMD-Moderate Mucoid	NMD-Moderate Mucoid		

Empty=no signs observed

FVR Post challenge Daily Body Temperature (°F)

Vaccinates - Group 1

Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1	100.4	100.0	101.1	100.0	103.4	101.6	101.2	101.1	100.3	101.4	101.2	101.5	101.5	101.7	100.0
2	101.6	100.8	100.9	100.9	104.7	101.3	101.3	101.5	101.4	101.1	101.7	101.1	101.7	101.3	101.0
3	100.8	100.8	100.7	100.3	101.4	103.6	101.2	101.1	100.0	100.5	101.4	101.2	100.6	100.7	101.2
4	101.3	100.3	101.3	100.6	101.5	101.2	101.3	102.3	102.4	102.3	102.0	101.1	102.1	101.7	101.9
5	100.2	101.2	100.9	100.8	100.5	102.9	100.8	101.5	102.5	102.4	102.2	102.1	101.2	102.2	101.0
6	101.4	100.9	101.0	101.0	104.7	101.4	101.1	101.2	100.7	101.5	102.0	101.7	102.3	101.9	101.3
7	100.6	101.2	100.7	100.4	101.7	102.3	101.6	102.4	101.4	101.4	102.4	100.9	101.9	102.1	100.9
8	100.9	100.3	100.7	100.8	103.4	100.6	100.2	100.3	100.4	100.0	101.2	101.5	100.8	101.7	102.0
9	101.4	100.8	100.8	101.3	104.6	101.4	101.2	100.4	100.0	99.9	100.6	100.0	101.2	100.7	100.5
10	101.2	100.6	101.3	101.1	104.4	101.5	101.8	100.7	101.2	101.5	101.7	101.8	101.2	101.7	100.3
11	100.9	100.1	101.0	101.3	103.8	101.0	101.3	101.7	100.7	100.6	100.4	101.5	101.3	101.2	100.7
12	100.9	100.4	101.0	100.0	101.9	101.8	100.6	101.2	101.3	101.4	101.7	101.8	101.8	101.7	101.4
13	100.6	99.9	100.3	100.1	100.8	100.8	101.3	100.1	101.3	100.7	101.2	101.0	101.0	101.4	101.0
14	100.0	100.5	100.4	100.2	101.3	102.2	101.8	100.9	100.7	100.8	102.2	100.9	101.8	101.5	101.7
15	101.5	101.0	101.0	100.9	101.3	102.0	100.8	100.8	100.6	100.1	100.8	101.4	100.9	101.0	100.4
16	101.2	101.1	101.5	101.1	101.8	102.8	101.2	101.7	101.7	101.3	101.5	102.3	101.7	101.1	101.1
17	101.2	100.8	100.9	101.5	102.9	101.9	101.2	100.8	101.1	100.9	101.0	100.6	101.4	100.0	100.3
18	100.8	100.5	101.1	101.3	102.1	100.4	101.1	101.2	101.3	101.3	101.5	101.1	101.4	100.1	100.8
19	100.8	100.4	100.8	101.1	103.8	103.1	101.5	102.8	102.5	102.6	102.6	101.9	102.1	102.3	101.9
20	101.2	101.1	101.0	101.5	101.8	102.1	101.7	102.4	102.5	102.4	103.1	102.4	102.2	101.3	101.3
21	100.3	100.0	100.5	101.7	104.1	101.8	101.9	102.2	102.5	101.7	101.4	100.8	100.7	100.7	99.9
22	100.6	101.2	101.1	100.7	103.3	101.2	101.0	101.9	101.2	101.2	101.1	100.5	101.3	101.4	100.2

FVR Post challenge Daily Body Temperature (°F)

Vaccinates - Group 2															
Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1	100.0	101.1	100.4	100.7	101.7	101.3	100.2	100.7	101.5	101.6	101.3	101.2	101.4	101.5	100.0
2	100.8	101.0	100.6	100.7	101.7	101.2	101.6	101.2	101.1	101.1	101.3	101.5	101.8	100.7	101.0
3	100.6	101.4	100.8	101.9	101.6	101.8	100.9	102.0	102.4	102.2	102.7	102.5	102.0	102.5	101.1
4	100.9	100.2	100.7	100.4	102.7	101.5	100.2	101.9	101.7	101.9	102.1	101.9	100.0	102.7	101.6
5	100.4	100.1	101.0	100.3	102.0	101.4	101.2	101.7	101.7	101.6	101.5	101.6	101.9	100.8	100.6
6	101.7	100.9	101.5	100.7	104.6	102.7	101.9	102.2	100.6	101.3	102.3	101.1	101.3	100.6	101.5
7	100.7	100.1	101.3	100.7	101.4	102.2	101.0	101.2	100.4	101.0	101.2	100.6	100.6	100.4	100.2
8	100.7	100.6	101.1	101.1	103.1	101.7	102.2	102.5	102.3	101.4	102.3	102.6	101.6	101.8	101.7
9	101.8	101.3	101.6	100.5	102.8	103.2	102.7	102.1	102.5	102.6	102.2	102.6	102.8	101.6	101.8
10	100.6	100.6	100.7	102.5	102.9	101.9	102.0	102.6	102.4	101.3	101.5	101.5	101.9	100.8	100.4

Non-Vaccinated Controls

Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1	100.7	101.1	101.2	100.4	102.0	105.0	102.0	105.0	101.4	102.2	101.3	101.7	101.8	100.0	100.8
2	101.0	100.3	101.1	100.6	101.4	103.3	101.2	102.3	103.2	101.8	102.5	102.5	101.2	102.2	100.0
3	101.3	101.5	102.0	101.2	101.6	105.3	101.2	101.8	103.5	103.5	101.6	100.5	101.3	101.9	101.7
4	101.5	100.7	101.3	101.2	103.6	101.7	104.0	102.0	102.7	101.1	101.1	101.6	101.4	101.2	101.1
5	102.1	101.4	101.7	101.4	102.1	103.5	101.0	104.7	101.5	102.6	101.4	101.4	102.4	100.8	100.6
6	101.6	101.3	101.3	100.5	103.0	101.8	102.6	103.6	103.4	100.7	101.7	101.0	102.2	100.5	101.0
7	101.3	100.4	101.2	100.9	104.6	101.3	102.8	102.0	103.0	100.5	101.3	101.8	101.7	100.0	100.5
8	101.1	100.3	101.4	100.7	103.7	102.5	103.9	102.4	102.4	101.2	101.4	101.9	101.8	100.6	101.7
9	100.5	100.0	100.9	100.0	102.0	100.9	101.2	105.5	101.8	102.3	102.4	101.5	101.4	101.1	100.0
10	101.5	101.4	101.6	101.1	103.8	102.2	104.3	102.2	102.0	100.6	101.4	100.8	100.7	100.9	100.0

Study Type	Efficacy
Pertaining to	Feline Panleukopenia Virus (FPV)
Study Purpose	To demonstrate effectiveness against FPV
Product Administration	Two doses administered 21 days apart subcutaneously (SC)
Study Animals	Thirty-three (33) cats 8 weeks of age. Cats were randomized into one vaccinated group of 23 cats and one group of 10 non-vaccinated controls.
Challenge Description	85 days post second vaccination all cats were challenged with virulent FPV.
Interval observed after challenge	Rectal temperatures and clinical signs were observed daily for 14 days post challenge.
Results	<p>Vaccinates and controls were evaluated for leukopenia (defined as a $\geq 50\%$ decrease in white blood cells from pre-challenge levels).</p> <p>Positive for Leukopenia: Vaccinates: 0/0 (0%) positive Controls: 9/10 (90%) positive</p> <p>Raw Data: Data tables are appended to the end of the summary.</p>
USDA Approval Date	June 30, 1999

White Blood Cell Counts (counts/uL blood) Following FPV Challenge

Non-Vaccinated Controls

Cat ID	Baseline Avg.	2DPC	4DPC	6DPC	8DPC	10DPC
1	18938	10890	8800	8360	7425	7810
2	11713	9405	6930	4125	5280	7865
3	12962	9735	4656	5610	3685	6325
4	11110	11000	4290	3630	4840	4510
5	12907	6105	4730	5555	6490	5005
6	15345	11440	3905	5280	9625	7425
7	14630	11550	5170	7095	7535	7920
8	13182	10945	5253	4565	8855	10340
9	12173	9240	7480	7810	8580	10120
10	12760	9405	8250	6050	15510	12045

Vaccinates

Cat ID	Baseline Avg.	2DPC	4DPC	6DPC	8DPC	10DPC
11	14777	12155	21725	19305	20845	18040
12	12888	12650	9295	13090	13970	13475
13	11293	9955	11825	14410	12375	10505
14	10102	9955	10945	11275	12980	10725
15	8855	7590	8250	11550	11165	9295
16	13475	11165	11495	10120	10890	13365
17	10560	7755	15180	10450	13090	10505
18	17600	16354	18755	23650	18810	13255
19	16262	13145	14190	15785	16500	15950
20	12797	9625	12375	16280	15345	11825
21	14758	11660	12430	11770	11660	12430
22	14080	10560	10285	13145	17765	20570
23	10908	8690	7370	9900	11935	7810
24	13548	10010	11770	15685	12870	12760
25	13237	10395	11495	13585	18700	10505
26	13640	12320	14080	16225	15840	13860
27	13182	10615	12925	12650	16885	11303
28	10102	8140	8525	9405	12595	11880
29	11807	9570	17160	14350	11770	14465
30	13787	9625	17050	13255	14740	11743
31	13732	12870	17160	15180	15620	10780
32	10835	9515	15840	8305	11220	9900
33	12357	8414	17380	10065	11055	10450

DPC = Days Post Challenge

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety of product under typical use conditions
Product Administration	A total of 716 cats, 282 eight weeks of age or younger and 434 greater than 8 weeks, were administered either one or two doses of vaccine 3-4 weeks apart by the subcutaneous route. A total of 1386 doses were administered.
Study Animals	Privately owned and commercial catteries
Challenge Description	NA
Interval observed after challenge	Observed for 30 minutes after vaccination and then daily for 2 weeks after each vaccination.
Results	Frequency of events is appended to the end of this summary.
USDA Approval Date	October 29, 1998

Summary of Reactions:

Reaction Type	up to 8 weeks of age				> 8 Weeks of Age				Sum of Doses	Percent
	<24h	>24h	Total by dose	%	<24h	>24h	Total by dose	%		
None	NA	NA	543	98.7%	NA	NA	785	93.4%	1328	95.82%
Fever	0	0	0	0.00%	2	0	2	0.24%	2	0.14%
Lethargy	3	0	3	0.55%	14	0	14	1.67%	17	1.23%
Vomiting	1	0	1	0.18%	2	0	2	0.24%	3	0.22%
Diarrhea	0	0	0	0.00%	2	0	2	0.24%	2	0.14%
Injection Site Soreness	4	0	4	0.73%	0	0	0	0.00%	4	0.29%
Anorexia									1	0.08%
Eye problem									5	0.38%
Lost to follow-up									10	0.72%
Unrelated Mortality*									14	1.06%
Total Doses			550				836		1386	

*Affirmed by licensee to have a non-vaccine cause.