



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	1585.20
True Name	Chlamydia Psittaci Vaccine, Killed Chlamydia
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Fel-O-Vax Pn-K - Elanco US Inc.
Date of Compilation Summary	October 16, 2020

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 Chlamydia Psittaci (FCP)
Study Purpose	To demonstrate effectiveness against FCP
Product Administration	Two doses administered 21 days apart subcutaneously (SC) or Intramuscular (IM).
Study Animals	Thirty (30) 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 10 non-vaccinated controls.
Challenge Description	21 days post second vaccination all cats were challenged with FCP.
Interval observed after challenge	Rectal temperatures and clinical signs were observed daily for 28 days post challenge.
Results	<p>Vaccinates and controls were evaluated per the criteria in 9 CFR 113.71.(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 9 CFR 113.71 (3) were met.</p> <p>Raw Data: Data tables are appended to the end of the summary.</p>
USDA Approval Date	April 13, 1990

Daily Rectal Temperatures Following FCP Challenge

		Vaccinates																														
Cat ID	Route	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC	15DPC	16DPC	17DPC	18DPC	19DPC	20DPC	21DPC	22DPC	23DPC	24DPC	25DPC	26DPC	27DPC	28DPC			
1	M	101.8	102.2	102.8	103.8	102.6	102.4	101.6	102.6	102.4	102.8	102.0	102.6	102.0	102.0	102.4	102.8	102.4	101.6	102.6	101.6	102.6	102.0	101.8	101.6	101.6	101.4	101.8	103.3	103.2		
2	M	101.9	104.0	101.9	102.6	101.4	102.2	101.6	102.0	101.4	102.2	101.8	101.9	102.6	102.0	102.4	102.4	102.4	102.2	101.6	101.7	101.8	102.2	101.4	101.6	101.6	101.7	101.4	101.8	102.0		
3	M	101.4	102.4	102.5	102.6	102.0	102.3	102.4	102.0	102.3	102.4	102.2	102.0	101.6	102.4	101.6	102.4	102.6	102.8	102.0	102.5	102.7	102.6	102.0	102.4	101.8	101.6	102.2	102.4	103.0		
4	M	101.4	102.6	103.2	103.4	102.6	102.4	102.2	102.4	102.6	102.6	102.6	103.0	102.2	101.8	102.2	102.4	102.4	102.2	102.4	102.4	102.2	102.2	102.0	101.8	102.4	102.0	102.2	102.0	102.6	103.0	
5	M	101.4	103.0	102.3	102.0	101.6	102.6	102.0	102.4	102.0	102.8	102.0	102.6	102.0	102.6	102.6	104.0	102.4	102.2	102.4	102.2	102.4	102.2	102.2	101.4	102.0	101.8	102.2	102.2	103.0	102.2	
6	M	101.8	103.2	102.4	103.6	102.6	102.0	101.6	102.6	102.5	102.6	102.0	103.4	102.2	102.0	101.6	104.0	103.4	101.4	102.2	102.2	102.2	102.2	101.6	101.8	102.0	102.4	102.0	102.4	102.4	102.0	
7	M	101.8	103.0	103.2	103.6	102.6	102.8	102.4	102.6	101.6	102.4	102.0	102.4	103.0	102.4	102.6	102.6	102.6	102.2	101.8	102.2	102.6	102.6	102.6	102.0	102.2	102.2	102.2	102.8	102.5	102.6	
8	M	101.4	101.6	103.2	102.6	101.8	101.6	101.6	101.6	101.4	102.0	101.8	102.0	101.6	102.2	101.6	101.6	101.6	101.8	101.4	101.7	101.8	102.0	101.0	102.0	101.2	101.8	101.6	102.4	103.0	103.0	
9	M	102.0	104.0	103.5	103.6	103.0	102.8	102.6	102.0	102.6	102.8	101.8	102.2	102.2	102.2	102.6	102.6	102.6	103.0	101.8	103.2	102.8	102.4	102.3	102.0	102.0	102.8	102.6	103.0	103.2	103.2	
10	M	101.8	102.8	102.7	103.8	102.7	102.6	102.2	101.4	102.4	102.6	102.0	103.3	NA	NA	NA	102.8	102.6	102.0	102.0	103.8	102.6	103.0	102.1	102.2	102.0	102.4	102.8	102.7	102.8	102.8	
11	SC	101.4	104.0	101.8	103.0	102.2	101.8	101.8	101.6	102.0	102.0	103.0	103.2	103.0	NA	103.2	102.4	102.8	102.0	102.0	103.4	102.2	103.0	102.6	102.2	102.0	102.4	103.0	104.2	103.4	103.4	
12	SC	102.2	102.8	103.0	103.0	103.0	101.4	101.8	102.8	101.6	102.8	102.4	101.6	101.8	102.2	102.0	104.4	102.2	101.8	102.2	102.6	102.2	102.2	101.0	101.8	101.7	102.0	102.2	102.5	103.2	103.2	
13	SC	101.8	103.0	103.4	103.6	103.0	102.6	103.2	102.4	102.4	102.6	102.6	102.0	102.4	101.8	102.4	102.8	102.8	102.8	102.4	103.2	102.8	102.2	102.4	102.8	102.0	102.0	102.4	102.8	102.4	102.4	
14	SC	102.2	102.8	103.0	102.6	101.4	102.4	102.2	101.8	101.6	102.2	101.8	101.7	101.8	101.6	101.6	101.4	102.6	102.2	102.6	102.6	102.6	102.2	103.4	104.0	103.4	102.8	103.6	103.8	103.8	103.2	
15	SC	102.4	103.2	102.8	102.4	101.4	102.0	101.4	102.2	102.3	103.0	101.8	102.4	104.0	101.6	101.6	101.8	102.2	103.0	102.2	102.4	101.4	102.2	101.6	102.0	101.8	102.2	102.0	101.8	102.2	102.2	
16	SC	102.2	102.5	102.6	102.6	101.8	102.2	102.0	101.6	102.2	102.4	102.8	102.2	102.0	102.0	102.0	104.2	104.2	104.2	102.2	102.2	102.0	102.8	101.4	101.8	102.0	103.4	102.0	102.0	102.0	102.6	
17	SC	102.6	102.4	103.1	103.2	102.5	102.4	102.8	102.8	102.1	102.2	102.4	101.6	103.0	102.4	103.4	102.6	102.8	101.4	103.2	103.2	102.8	102.0	101.8	102.4	102.4	102.4	102.4	102.8	103.0	103.8	103.8
18	SC	101.6	101.6	102.5	103.8	101.8	102.6	102.6	101.4	101.6	102.2	102.0	102.4	101.8	102.2	102.6	103.4	103.2	102.4	102.1	102.0	102.0	102.2	101.8	102.0	101.8	102.0	101.6	101.8	102.6	102.6	
19	SC	102.6	103.9	103.1	103.0	102.4	102.4	102.6	101.8	102.2	103.0	102.0	101.8	103.2	103.0	102.2	102.6	102.2	101.4	102.4	102.4	101.6	102.2	101.6	102.0	101.8	102.6	103.0	102.4	102.2	102.2	
20	SC	101.8	102.2	102.2	103.0	101.6	102.0	101.4	101.1	101.6	102.4	102.0	102.3	101.4	102.2	102.0	101.4	101.4	101.8	101.4	102.0	101.6	101.8	102.2	102.2	102.6	102.2	102.2	102.0	102.6	102.6	

No Vaccinated Controls

Cat ID	Route	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC	15DPC	16DPC	17DPC	18DPC	19DPC	20DPC	21DPC	22DPC	23DPC	24DPC	25DPC	26DPC	27DPC	28DPC	
1		101.8	102.4	102.5	102.4	102.4	102.8	102.0	102.0	102.6	103.0	102.8	103.6	104.0	103.8	104.2	105.2	104.2	104.8	105.5	104.8	103.8	102.4	103.8	103.8	103.6	102.8	103.2	103.6	103.6
2		103.0	102.8	102.7	102.0	101.8	102.4	102.4	102.6	102.3	102.8	102.8	103.3	102.8	102.6	103.2	104.4	102.4	105.2	105.2	105.0	103.8	104.4	104.0	104.0	104.1	103.8	103.4	103.3	103.6
3		102.4	103.2	103.5	103.6	103.0	102.2	102.8	102.4	101.7	102.6	102.6	103.4	103.4	102.8	104.4	103.8	104.8	104.8	104.6	103.8	102.6	102.1	103.4	103.0	103.6	103.2	104.0	103.0	103.0
4		101.4	102.8	102.8	103.0	101.6	102.2	101.4	101.8	102.2	102.0	102.8	103.6	102.4	101.8	102.2	103.2	103.6	102.6	103.1	103.2	104.0	103.4	103.4	103.8	104.6	103.4	104.3	103.0	103.0
5		101.5	102.6	102.1	102.4	102.0	101.6	101.8	101.4	101.4	102.0	102.0	102.5	103.8	105.4	104.2	104.2	104.2	103.4	103.6	103.4	103.4	102.2	103.2	103.4	103.1	103.2	103.0	102.6	103.4
6		103.0	102.4	103.5	102.4	102.4	103.0	102.4	101.8	102.4	103.2	101.8	101.7	103.0	102.8	102.6	102.8	102.8	103.0	104.2	103.2	103.2	102.6	102.4	102.4	102.8	103.2	103.0	103.3	103.0
7		102.4	102.6	103.1	103.6	103.0	102.2	101.8	102.2	101.6	102.6	102.0	101.8	102.8	102.6	102.6	103.8	103.2	103.8	104.4	104.6	104.6	101.4	103.3	102.8	102.8	103.2	102.8	102.5	102.0
8		101.4	103.0	103.0	103.4	103.2	102.0	101.8	102.4	102.2	102.2	102.4	102.8	101.8	103.8	104.0	104.4	104.4	104.6	104.2	104.0	103.8	103.8	102.8	103.0	103.6	104.6	103.4	103.3	103.0
9		102.2	103.0	102.1	103.0	103.0	102.2	101.6	102.0	101.6	102.4	102.6	102.4	102.6	102.0	102.2	103.8	103.8	104.6	105.0	103.8	104.0	104.4	104.4	104.0	102.6	104.6	103.4	102.3	102.2
10		101.4	104.0	104.2	104.4	103.6	103.8	103.4	101.4	103.8	103.2	102.2	102.4	104.2	103.4	105.0	104.2	104.2	102.8	104.4	104.0	104.5	104.8	101.6	104.0	104.0	104.0	103.4	103.8	103.0

Study Type	Safety																																																												
Pertaining to	All																																																												
Study Purpose	Demonstrate safety of product under typical use conditions																																																												
Product Administration	A total of 416 cats of various ages and breeds were administered 1 dose of vaccine. In addition, 308 of the 416 animals were given a second dose 2- 3 weeks later.																																																												
Study Animals	Client-owned cats presenting to a veterinary clinic.																																																												
Challenge Description	NA																																																												
Interval observed after challenge	Followed for 4-7 days after each vaccination.																																																												
Results	<p>Frequency of Adverse Events:</p> <p style="text-align: center;">Total number of Doses Administered = 724</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">1st Dose</th> <th style="text-align: center;">2nd Dose</th> <th style="text-align: center;">Total</th> <th style="text-align: center;">Percent per # of Doses</th> </tr> </thead> <tbody> <tr> <td>No Adverse Events</td> <td style="text-align: center;">370</td> <td style="text-align: center;">298</td> <td style="text-align: center;">668</td> <td style="text-align: center;">92.27%</td> </tr> <tr> <td>Look at injection site</td> <td style="text-align: center;">4</td> <td style="text-align: center;">1</td> <td style="text-align: center;">5</td> <td style="text-align: center;">0.69%</td> </tr> <tr> <td>Turn in Circles</td> <td style="text-align: center;">1</td> <td style="text-align: center;">0</td> <td style="text-align: center;">1</td> <td style="text-align: center;">0.14%</td> </tr> <tr> <td>Scratch at site</td> <td style="text-align: center;">2</td> <td style="text-align: center;">0</td> <td style="text-align: center;">2</td> <td style="text-align: center;">0.28%</td> </tr> <tr> <td>Chew at site</td> <td style="text-align: center;">9</td> <td style="text-align: center;">0</td> <td style="text-align: center;">9</td> <td style="text-align: center;">1.24%</td> </tr> <tr> <td>Vocalize as in pain</td> <td style="text-align: center;">12</td> <td style="text-align: center;">1</td> <td style="text-align: center;">13</td> <td style="text-align: center;">1.80%</td> </tr> <tr> <td>Lethargy</td> <td style="text-align: center;">24*</td> <td style="text-align: center;">9*</td> <td style="text-align: center;">33</td> <td style="text-align: center;">4.56%</td> </tr> <tr> <td>Anorexia</td> <td style="text-align: center;">1</td> <td style="text-align: center;">0</td> <td style="text-align: center;">1</td> <td style="text-align: center;">0.14%</td> </tr> <tr> <td>Soreness</td> <td style="text-align: center;">3</td> <td style="text-align: center;">2</td> <td style="text-align: center;">5</td> <td style="text-align: center;">0.69%</td> </tr> <tr> <td>Swelling or Nodule</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0.00%</td> </tr> <tr> <td>Other</td> <td style="text-align: center;">4</td> <td style="text-align: center;">1</td> <td style="text-align: center;">5</td> <td style="text-align: center;">0.69%</td> </tr> </tbody> </table> <p>* It was noted that a large number of test cats were classified to have lethargy. Thirty-one (31) came from the same site location. Upon conversation with the veterinarian, he commented that these cats were observed to be temporarily tired or mellow after vaccination, which were not considered unacceptable or significant reactions by him.</p>		1st Dose	2nd Dose	Total	Percent per # of Doses	No Adverse Events	370	298	668	92.27%	Look at injection site	4	1	5	0.69%	Turn in Circles	1	0	1	0.14%	Scratch at site	2	0	2	0.28%	Chew at site	9	0	9	1.24%	Vocalize as in pain	12	1	13	1.80%	Lethargy	24*	9*	33	4.56%	Anorexia	1	0	1	0.14%	Soreness	3	2	5	0.69%	Swelling or Nodule	0	0	0	0.00%	Other	4	1	5	0.69%
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