Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	1421.20
True Name	Canine Parainfluenza Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	September 14, 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	Canine Parainfluenza (CPI)
Study Purpose	Efficacy against respiratory disease due to CPI
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	1984

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety of product under typical use conditions
Product Administration	2 Doses administered at a 3-week interval by the SQ route
Study Animals	628 privately owned canines were included in the final analysis. More than one-third of the canines (n=214) enrolled in the study were ≤8 weeks (≤59 days of age) at the time of first vaccination. 639 Total dogs were enrolled but 11 did not complete the study.
Challenge Description	NA
Interval observed after challenge	Canines 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 14 days.
Results	See table appended below for frequency of adverse events:

Adverse Event	Number ≤59 days old	Percent ≤59 days old	Number >59 days old	Percent >59 days old	Total number	Percent of all animals
No adverse events	157	73.36	374	90.34	531	84.55
Diarrhea*	50	23.36	11	2.66	61	9.71
Gastroenteritis	24	11.21	4	.97	28	4.46
Injection site lump	3	1.4	10	2.42	13	2.07
Depression	8	3.74	1	0.24	9	1.43
Anorexia	8	3.74	0	0	8	1.27
Decreased appetite	4	1.87	4	0.97	8	1.27
Not drinking	8	3.74	0	0	8	1.27
Mortality (affirmed by licensee to have cause other than vaccination)	4	1.87	2	0.48	6	0.96
Injection site pain	4	1.87	1	0.24	5	0.80
Injection site granuloma	0	0	4	0.97	4	0.64
Abdominal pain	3	1.4	0	0	3	0.48
Cough	0	0	3	0.72	3	0.48
Hypersalivation	3	1.4	0	0	3	0.48
Hyperactivity	0	0	2	0.48	2	0.32
Aggression	0	0	1	0.24	1	0.16
Corneal edema	0	0	1	0.24	1	0.16
Digestive tract disorder (no other signs)	1	0.47	0	0	1	0.16
Fever	0	0	1	0.24	1	0.16

	Fungal skin infection	1	0.47	0	0	1	0.16
	Hot Spot (pyotraumatic dermatitis)	0	0	1	0.24	1	0.16
	Injection site abscess	0	0	1	0.24	1	0.16
	Joint pain	0	0	1	0.24	1	0.16
	Local swelling (not application site)	0	0	1	0.24	1	0.16
	Miscellaneous eating disorder NOS	0	0	1	0.24	1	0.16
	Nasal Discharge	1	0.47	0	0	1	0.16
	Ocular Discharge	0	0	1	0.24	1	0.16
	Polydipsia	0	0	1	0.24	1	0.16
	Skin swelling	0	0	1	0.24	1	0.16
	Sneezing	0	0	1	0.24	1	0.16
	Tremor	0	0	1	0.24	1	0.16
	Weakness	0	0	1	0.24	1	0.16
	*78 animals had confirmed diagnoses of at least one potential cause for diarrhea and gastroenteritis not attributable to vaccination (Several animals had more than one disease).						
USDA Approval Date	February 28, 2017						