Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Vetmedica, Inc.
USDA Vet Biologics Establishment Number	124
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	December 05, 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
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.

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
Observation interval after last treatment	Canines were observed for 30 min following the first vaccination and daily till the second vaccination. Each animal was then observed for 30 min following the second vaccination and again daily for 14 days.
Results	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	0.97	28	4.46
Injection site lump	3	1.40	10	2.42	13	2.07
Depression	8	3.74	1	0.24	9	1.43
Anorexia	8	3.74	0	0.00	8	1.27
Decreased appetite	4	1.87	4	0.97	8	1.27
Not drinking	8	3.74	0	0.00	8	1.27
Mortality Affirmed by licensee to have probable 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	0.00	4	0.97	4	0.64
Abdominal pain	3	1.40	0	0.00	3	0.48
Cough	0	0.00	3	0.72	3	0.48
Hypersalivation	3	1.40	0	0.00	3	0.48
Hyperactivity	0	0.00	2	0.48	2	0.32
Aggression	0	0.00	1	0.24	1	0.16
Corneal edema	0	0.00	1	0.24	1	0.16
Digestive tract disorder NOS	1	0.47	0	0.00	1	0.16
Fever	0	0.00	1	0.24	1	0.16
Fungal skin infection NOS	1	0.47	0	0.00	1	0.16
Hot spot (pyotraumatic dermatitis)	0	0.00	1	0.24	1	0.16

	Injection site abscess	0	0.00	1	0.24	1	0.16
	Joint pain	0	0.00	1	0.24	1	0.16
	Local swelling (not application site)	0	0.00	1	0.24	1	0.16
	Miscellaneous eating disorder NOS	0	0.00	1	0.24	1	0.16
	Nasal discharge	1	0.47	0	0.00	1	0.16
	Ocular discharge	0	0.00	1	0.24	1	0.16
	Polydipsia	0	0.00	1	0.24	1	0.16
	Skin swelling	0	0.00	1	0.24	1	0.16
	Sneezing	0	0.00	1	0.24	1	0.16
	Tremor	0	0.00	1	0.24	1	0.16
	Weakness	0	0.00	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						