Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Vetmedica, Inc.
USDA Vet Biologics Establishment Number	124
Product Code	2100.00
True Name	Bordetella Bronchiseptica Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	December 06, 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	Bordetella bronchiseptica (Bb)
Study Purpose	Pivotal Efficacy against respiratory disease due to Bb
Product Administration	Two doses administered subcutaneously 21 days apart
Study Animals	30 Dogs, 7 weeks old, randomly divided into 15 vaccinates and 15 placebo controls
Challenge Description	Bb was administered 14 days after the last vaccination
Interval observed after challenge	Dogs were observed for clinical signs 2x daily for 14 days post challenge.
Results	Dogs were considered affected by Bb challenge if coughing was observed for two or more days post challenge. Positive Bb Clinical results: Vaccinates: 4/15 (27%) positive Controls: 14/15 (93%) positive See the attached table with the clinical observations for coughing.
USDA Approval Date	April 4, 2013

Individual Clinical Scores for Coughing

study # 2011121

Experimental Vaccine Group

Dog	-2DPC	-1DPC	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	1	1	0	1	1	0	0	1	0	0	1	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
4	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	0	0
5	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0

Placebo Control Group

Dog	-2DPC	-1DPC	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
16	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0
17	0	0	0	0	1	1	1	0	1	0	0	0	0	0	1	0	0
18	0	0	0	0	0	1	1	1	1	0	0	0	0	0	0	1	0
19	0	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	0
20	0	0	0	0	0	1	1	1	1	1	1	1	1	0	0	0	0
21	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0
22	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1
23	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	1	0	1	0	0	1	0	0	0	0	0	0
25	0	0	0	0	0	0	1	1	1	1	1	1	0	0	0	0	0
26	0	0	0	0	0	0	1	1	1	0	1	1	0	1	1	0	1
27	0	0	0	0	1	1	1	1	1	1	1	1	0	1	1	1	0
28	0	0	0	0	0	1	1	1	1	0	1	1	1	1	1	0	0
29	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0
30	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0

1 - cough observed

0 - no cough observed

* Dogs were considered affected by Bb challenge if coughing was observed for two or more days post challenge.

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						