Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1081.02
True Name	Bordetella Bronchiseptica Vaccine, Avirulent Live Culture
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Bronchi-Shield Oral - Boehringer Ingelheim (Canada) Ltd. Bronchi-Shield Oral - No distributor specified Protech Bronchi-Shield Oral - Boehringer Ingelheim Animal Health Australia Pty. Ltd. Protech Bronchi-Shield Oral - No distributor specified
Date of Compilation Summary	January 26, 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	*Bordetella bronchiseptica*
Study Purpose	To demonstrate effectiveness against *Bordetella bronchiseptica* (Kennel Cough) in 8-week-old puppies.
Product Administration	One dose was administered by the oral route in the buccal pouch
Study Animals	Forty-four (44) 8-week-old puppies negative for *B. bronchiseptica* by tracheal swab were used in the final study analysis. Animals were allocated into one group of 15 puppies vaccinated with combination vaccine containing *B. bronchiseptica*, canine parainfluenza, and canine adenovirus 2; one group of 14 puppies vaccinated with vaccine containing only *Bordetella bronchiseptica*; and one placebo control group of 15 puppies.
Challenge Description	Five weeks after vaccination, animals were challenged with *Bordetella bronchiseptica*.
Interval observed after challenge	Puppies were monitored for 30 minutes twice daily for 14 days after challenge for presence of clinical signs.
Results	A puppy was considered positive for tracheobronchitis by *B. bronchiseptica* if it was observed coughing for two or more days. Number affected: Combination Vaccine Group: 0/15 Monovalent Vaccine Group: 1/14 Placebo Controls: 15/15 See the next page for data.
USDA Approval Date	October 19, 2011

	Cough (C) observed on the indicated Days After Challenge In Placebo Control Puppies														
Dog ID	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1				C			C		C						
2				C		C		C							
3				C	C	C		C		C		C		C	
4					C			C							
5						C		C	C	C					
6				C	C			C	C						
7				C	C			C				C			
8				C	C	C	C	C	C	C		C	C		
9				C	C	C	C	C	C	C					
10					C	C	C	C	C	C			C		
11				C	C	C	C	C							
12				C	C	C	C	C		C	C	C	C	C	
13				C	C	C	C	C							
14				C	C	C	C	C	C	C					C
15				C	C	C	C		C						C

	Cough (C) observed on the indicated Days After Challenge In Combination vaccine group														
Dog ID	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1															
2															
3															
4															
5															
6															
7															
8															
9															
10												C			
11															
12															
13															
14															
15															

	Cough (C) observed on the indicated Days After Challenge In Monovalent Vaccine Group														
Dog ID	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1															
2			C												
3															
4															
5															
6															
7															
8															
9							C		C						
10															
11															
12															
13															
14															
15															

Study Type	Efficacy
Pertaining to	*Bordetella bronchiseptica*
Study Purpose	Demonstration of efficacy against *Bordetella bronchiseptica*
Product Administration	Intranasal
Study Animals	Canine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	June 16, 1994

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>All fractions</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate safety of product under typical use conditions</td></tr>
<tr><td>Product Administration</td><td>Each animal was given 1 dose intranasally, as a 1 mL dose, by inoculating 0.5 mL into each nostril.</td></tr>
<tr><td>Study Animals</td><td>A total of 696 dogs were enrolled in the study. Of these dogs, 447 were puppies ranging from 4 to 12 weeks of age. Four independent sites were used in the study.</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>No challenge. Animals were observed for 1 hour after vaccination and daily for two weeks after vaccination.</td></tr>
<tr><td>Results</td><td>Frequency of adverse events:
<table>
<tr><th></th><th>Number of Animals</th><th>Percent of Animals</th></tr>
<tr><td>No Adverse Events</td><td>675</td><td>96.98%</td></tr>
<tr><td>Lethargy</td><td>3</td><td>0.43%</td></tr>
<tr><td>Anorexia</td><td>1</td><td>0.14%</td></tr>
<tr><td>Sneezing</td><td>5</td><td>0.72%</td></tr>
<tr><td>Cough</td><td>10</td><td>1.44%</td></tr>
<tr><td>Rhinitis</td><td>7</td><td>1.01%</td></tr>
<tr><td>Death</td><td>3*</td><td>0.43%</td></tr>
</table>
*Affirmed by study investigator to have cause other than vaccination</td></tr>
<tr><td>USDA Approval Date</td><td>February 5, 1996</td></tr>
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Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions
Product Administration	Oral
Study Animals	Canine
Challenge Description	Not applicable
Interval observed after challenge	Not applicable
Results	Study data are not available