Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	1081.02
True Name	Bordetella Bronchiseptica Vaccine, Avirulent Live Culture
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Bronchi-Shield Oral - Elanco US Inc. Bronchi-Shield Oral - No distributor specified
Date of Compilation Summary	June 30, 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*
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 Raw data: A data table is appended to the end of this summary.
USDA Approval Date	October 19, 2011

	Cough 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 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 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															

C = Cough

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>ALL</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 1mL dose, by inoculating 0.5mL into each nostril.</td></tr>
<tr><td>Study Animals</td><td>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>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>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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