Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1081.04
True Name	Bordetella Bronchiseptica Vaccine, Avirulent Live Culture
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Recombitek Oral Bordetella - Boehringer Ingelheim Animal Health Mexico Recombitek Oral Bordetella - No distributor specified
Date of Compilation Summary	January 06, 2021

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	Demonstrate efficacy against respiratory disease due to *Bordetella bronchiseptica*
Product Administration	One dose administered orally
Study Animals	Eight week old dogs divided into two groups: Group 1 vaccinated Group 2 placebo (control) vaccine
Challenge Description	*Bordetella bronchiseptica* administered 5 weeks post vaccination
Interval observed after challenge	During the two-week post-challenge observation period, the dogs were observed twice a day.
Results	Vaccinates and controls were evaluated based on coughing on at least two consecutive days during the post-challenge observation period. Vaccinates : 1/16 Controls: 12/16 Raw data on next page.

	Cough observed on the indicated Days Post-Challenge in Control Group														
	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Dog ID															
1				C	C	C	C	C	C	C					
2															
3					C	C		C	C						
4			C	C	C	C	C		C						
5						C	C			C		C			
6						C	C	C							
7															
8				C		C	C	C							
9			C	C	C	C	C	C	C	C	C	C	C		
10					C	C		C		C		C			
11															
12				C	C	C	C		C	C					
13								C	C	C	C	C			
14				C		C		C							
15					C					C		C	C		
16				C	C	C	C	C	C	C					

	Cough observed on the indicated Days Post-Challenge in Vaccine Group														
	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Dog ID															
1															
2															
3															
4															
5				C		C	C	C							
6										C					
7															
8															
9															
10															
11													C		
12							C								
13															
14											C				
15															
16									C						

C = cough observed

USDA Approval Date	May 20, 2016

Study Type	Efficacy
Pertaining to	*Bordetella bronchiseptica*
Study Purpose	Demonstrate efficacy against respiratory disease due to *Bordetella bronchiseptica*
Product Administration	One dose administered orally
Study Animals	Eight week old dogs divided into two groups: Group 1 vaccinated Group 2 placebo (control) vaccine
Challenge Description	*Bordetella bronchiseptica* administered ~13 months post vaccination (Day 406 after vaccination)
Interval observed after challenge	During the two-week post-challenge observation period, the dogs were observed twice a day.
Results	Vaccinates and controls were evaluated based on coughing on at least two consecutive days during the post-challenge observation period. A dog was considered coughing for a day if it was observed during either the AM or PM observation with spontaneous cough. Vaccinates : 0/17 Controls: 13/17 Raw data on next page.
USDA Approval Date	April 24, 2020

Cough observed on the indicated Days Post-Challenge in the Control Group

Day			Animal ID																
		OP	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
	407	AM	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
		PM	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1
	408	AM	1	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	1
		PM	1	0	1	0	0	0	1	0	0	0	0	1	1	0	1	0	1
	409	AM	1	1	1	0	1	0	1	0	0	0	0	1	1	1	1	0	1
		PM	1	0	0	0	1	1	1	0	1	0	0	1	1	1	1	1	1
	410	AM	1	0	1	0	1	0	0	0	0	0	0	1	1	1	1	1	1
		PM	1	1	1	0	1	0	1	1	1	0	0	1	1	1	1	1	1
	411	AM	1	1	1	1	1	1	1	0	0	0	0	1	1	1	1	1	1
		PM	1	1	1	0	1	1	1	0	1	0	0	1	1	1	1	1	1
	412	AM	1	1	1	0	1	1	1	0	1	0	0	1	1	1	1	1	0
		PM	1	1	1	0	1	1	0	0	0	0	0	1	1	1	0	1	1
	413	AM	1	1	1	0	1	0	1	0	0	0	0	1	1	1	1	1	1
		PM	1	1	1	0	1	1	0	0	0	0	0	1	1	1	1	1	1
	414	AM	1	0	1	0	1	1	0	0	0	0	0	1	1	1	1	1	1
		PM	1	1	1	0	1	0	1	0	0	0	0	1	0	1	1	1	1
	415	AM	0	1	1	0	0	0	1	0	0	0	0	0	1	0	1	0	1
		PM	1	1	1	0	0	0	0	0	0	0	0	0	1	1	1	1	1
	416	AM	1	0	0	0	1	0	1	0	0	0	0	1	1	1	1	0	1
		PM	1	1	1	0	1	0	0	0	0	0	0	1	1	0	1	0	1
	417	AM	0	1	0	0	0	0	1	0	0	0	0	1	0	1	0	1	1
		PM	0	1	0	0	0	0	1	0	0	0	0	1	1	0	0	1	1
	418	AM	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1
		PM	1	1	1	0	1	0	0	0	0	0	0	1	1	0	0	0	1
	419	AM	0	1	0	0	0	0	0	0	0	0	0	1	1	0	0	0	1
		PM	1	0	0	0	0	0	1	0	0	0	0	0	1	0	1	0	1
	420	AM	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
		PM	1	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	1

1 = cough observed during observation period (OP)

Cough observed on the indicated Days Post-Challenge in the Vaccine Group

Day			Animal ID																
		OP	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
	407	AM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		PM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	408	AM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		PM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	409	AM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		PM	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	410	AM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		PM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	411	AM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		PM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	412	AM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		PM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	413	AM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		PM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	414	AM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		PM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	415	AM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		PM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	416	AM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		PM	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	417	AM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		PM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	418	AM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		PM	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	419	AM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		PM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	420	AM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		PM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

1 = cough observed during observation period (OP)

<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>One dose administered orally</td></tr>
<tr><td>Study Animals</td><td>758 dogs divided into two groups
≤ 8 weeks of age: 268
> 8 weeks of age: 490</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed for 30 minutes post-vaccination. Daily owner observations were conducted for 14 days after vaccination. At 14 days or later, the Site Investigator examined the animal.</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th>Adverse event†</th><th>Number in 758 doses</th></tr>
<tr><td>Diarrhea</td><td>30</td></tr>
<tr><td>Emesis</td><td>24</td></tr>
<tr><td>Lethargy</td><td>11</td></tr>
<tr><td>Sneezing</td><td>8</td></tr>
<tr><td>Hyperthermia</td><td>6</td></tr>
<tr><td>Digestive tract disorder</td><td>4</td></tr>
<tr><td>Cough</td><td>4</td></tr>
<tr><td>Appetite disorder</td><td>2</td></tr>
<tr><td>Skin textural change</td><td>2</td></tr>
<tr><td>Eye disorder</td><td>2</td></tr>
<tr><td>Nasal cavity disorder</td><td>2</td></tr>
<tr><td>Pruritis</td><td>2</td></tr>
<tr><td>Other*</td><td>12</td></tr>
</table>
*Adverse events in this category were decreased range of motion/painful neck, foul smelling urine, flea dirt/fleas, medial pinnal dermatitis, injuries from dog fight, restlessness, increased ear wax, unhappy.
</td></tr>
<tr><td>USDA Approval Date</td><td>December 5, 2017</td></tr>
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