



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Merial, Inc.
USDA Vet Biologics Establishment Number	298
Product Code	1081.01
True Name	Bordetella Bronchiseptica Vaccine, Avirulent Live Culture
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Recombitek Oral Bordetella - No distributor specified
Date of Compilation Summary	December 21, 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	<i>Bordetella bronchiseptica</i>
Study Purpose	Demonstrate efficacy against respiratory disease due to <i>Bordetella bronchiseptica</i>
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	<i>Bordetella bronchiseptica</i> 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	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	Safety																												
Pertaining to	All																												
Study Purpose	Demonstrate safety of product under typical use conditions																												
Product Administration	One dose administered orally																												
Study Animals	758 dogs divided into two groups ≤ 8 weeks of age: 268 > 8 weeks of age: 490																												
Challenge Description	Not applicable																												
Interval observed after challenge	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.																												
Results	<table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Adverse event†</th> <th>Number in 758 doses</th> </tr> </thead> <tbody> <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> </tbody> </table> <p>*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.</p>	Adverse event†	Number in 758 doses	Diarrhea	30	Emesis	24	Lethargy	11	Sneezing	8	Hyperthermia	6	Digestive tract disorder	4	Cough	4	Appetite disorder	2	Skin textural change	2	Eye disorder	2	Nasal cavity disorder	2	Pruritis	2	Other*	12
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