



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	2100.00
True Name	Bordetella Bronchiseptica Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	September 14, 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.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Bordetella bronchiseptica (Bb)
<b>Study Purpose</b>	Efficacy against respiratory disease due to Bb
<b>Product Administration</b>	Two doses administered subcutaneously 21 days apart
<b>Study Animals</b>	30 Dogs, 7 weeks old, randomly divided into 15 vaccinates and 15 placebo controls
<b>Challenge Description</b>	Bb was administered 14 days after the last vaccination
<b>Interval observed after challenge</b>	Dogs were observed for clinical signs 2x daily for 14 days post challenge.
<b>Results</b>	<p>Dogs were considered affected by Bb challenge if coughing was observed for two or more days post challenge.</p> <p>Positive Bb Clinical results:  Vaccinates: 4/15 (27%) positive  Controls: 14/15 (93%) positive</p> <p>See the attached table with the clinical observations for coughing.</p>
<b>USDA Approval Date</b>	April 4, 2013

Individual Clinical Scores for Coughing

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.

<b>Study Type</b>	Safety																																																																																																																																																	
<b>Pertaining to</b>	ALL																																																																																																																																																	
<b>Study Purpose</b>	Demonstrate safety of product under typical use conditions																																																																																																																																																	
<b>Product Administration</b>	2 Doses administered at a 3-week interval by the SQ route																																																																																																																																																	
<b>Study Animals</b>	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.																																																																																																																																																	
<b>Challenge Description</b>	NA																																																																																																																																																	
<b>Interval observed after challenge</b>	Canines were observed for 30 minutes following the first vaccination and daily till the second vaccination. Each animal was then observed for 30 minutes following the second vaccination and again daily for 14 days.																																																																																																																																																	
<b>Results</b>	See table appended below for frequency of adverse events:																																																																																																																																																	
	<table border="1"> <thead> <tr> <th>Adverse Event</th> <th>Number ≤59 days old</th> <th>Percent ≤59 days old</th> <th>Number &gt;59 days old</th> <th>Percent &gt;59 days old</th> <th>Total number</th> <th>Percent of all animals</th> </tr> </thead> <tbody> <tr> <td>No adverse events</td> <td>157</td> <td>73.36</td> <td>374</td> <td>90.34</td> <td>531</td> <td>84.55</td> </tr> <tr> <td>Diarrhea*</td> <td>50</td> <td>23.36</td> <td>11</td> <td>2.66</td> <td>61</td> <td>9.71</td> </tr> <tr> <td>Gastroenteritis</td> <td>24</td> <td>11.21</td> <td>4</td> <td>.97</td> <td>28</td> <td>4.46</td> </tr> <tr> <td>Injection site lump</td> <td>3</td> <td>1.4</td> <td>10</td> <td>2.42</td> <td>13</td> <td>2.07</td> </tr> <tr> <td>Depression</td> <td>8</td> <td>3.74</td> <td>1</td> <td>0.24</td> <td>9</td> <td>1.43</td> </tr> <tr> <td>Anorexia</td> <td>8</td> <td>3.74</td> <td>0</td> <td>0</td> <td>8</td> <td>1.27</td> </tr> <tr> <td>Decreased appetite</td> <td>4</td> <td>1.87</td> <td>4</td> <td>0.97</td> <td>8</td> <td>1.27</td> </tr> <tr> <td>Not drinking</td> <td>8</td> <td>3.74</td> <td>0</td> <td>0</td> <td>8</td> <td>1.27</td> </tr> <tr> <td>Mortality (affirmed by licensee to have cause other than vaccination)</td> <td>4</td> <td>1.87</td> <td>2</td> <td>0.48</td> <td>6</td> <td>0.96</td> </tr> <tr> <td>Injection site pain</td> <td>4</td> <td>1.87</td> <td>1</td> <td>0.24</td> <td>5</td> <td>0.80</td> </tr> <tr> <td>Injection site granuloma</td> <td>0</td> <td>0</td> <td>4</td> <td>0.97</td> <td>4</td> <td>0.64</td> </tr> <tr> <td>Abdominal pain</td> <td>3</td> <td>1.4</td> <td>0</td> <td>0</td> <td>3</td> <td>0.48</td> </tr> <tr> <td>Cough</td> <td>0</td> <td>0</td> <td>3</td> <td>0.72</td> <td>3</td> <td>0.48</td> </tr> <tr> <td>Hypersalivation</td> <td>3</td> <td>1.4</td> <td>0</td> <td>0</td> <td>3</td> <td>0.48</td> </tr> <tr> <td>Hyperactivity</td> <td>0</td> <td>0</td> <td>2</td> <td>0.48</td> <td>2</td> <td>0.32</td> </tr> <tr> <td>Aggression</td> <td>0</td> <td>0</td> <td>1</td> <td>0.24</td> <td>1</td> <td>0.16</td> </tr> <tr> <td>Corneal edema</td> <td>0</td> <td>0</td> <td>1</td> <td>0.24</td> <td>1</td> <td>0.16</td> </tr> <tr> <td>Digestive tract disorder (no other signs)</td> <td>1</td> <td>0.47</td> <td>0</td> <td>0</td> <td>1</td> <td>0.16</td> </tr> <tr> <td>Fever</td> <td>0</td> <td>0</td> <td>1</td> <td>0.24</td> <td>1</td> <td>0.16</td> </tr> </tbody> </table>						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	.97	28	4.46	Injection site lump	3	1.4	10	2.42	13	2.07	Depression	8	3.74	1	0.24	9	1.43	Anorexia	8	3.74	0	0	8	1.27	Decreased appetite	4	1.87	4	0.97	8	1.27	Not drinking	8	3.74	0	0	8	1.27	Mortality (affirmed by licensee to have 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	4	0.97	4	0.64	Abdominal pain	3	1.4	0	0	3	0.48	Cough	0	0	3	0.72	3	0.48	Hypersalivation	3	1.4	0	0	3	0.48	Hyperactivity	0	0	2	0.48	2	0.32	Aggression	0	0	1	0.24	1	0.16	Corneal edema	0	0	1	0.24	1	0.16	Digestive tract disorder (no other signs)	1	0.47	0	0	1	0.16	Fever	0	0	1	0.24	1	0.16
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	Fungal skin infection	1	0.47	0	0	1	0.16
	Hot Spot (pyotraumatic dermatitis)	0	0	1	0.24	1	0.16
	Injection site abscess	0	0	1	0.24	1	0.16
	Joint pain	0	0	1	0.24	1	0.16
	Local swelling (not application site)	0	0	1	0.24	1	0.16
	Miscellaneous eating disorder NOS	0	0	1	0.24	1	0.16
	Nasal Discharge	1	0.47	0	0	1	0.16
	Ocular Discharge	0	0	1	0.24	1	0.16
	Polydipsia	0	0	1	0.24	1	0.16
	Skin swelling	0	0	1	0.24	1	0.16
	Sneezing	0	0	1	0.24	1	0.16
	Tremor	0	0	1	0.24	1	0.16
	Weakness	0	0	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).						
<b>USDA Approval Date</b>	February 28, 2017						