Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	12X1.21
True Name	Canine Adenovirus Type 2-Parainfluenza-Bordetella Bronchiseptica Vaccine, Modified Live Virus & Avirulent Live Culture
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Protech Bronchi-shield III - Boehringer Ingelheim Animal Health Australia Pty. Ltd. Protech Bronchi-shield III - 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	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

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<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>
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*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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