Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	12X1.20
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)	Bronchi-Shield III - Boehringer Ingelheim (Canada) Ltd. Bronchi-Shield III - No distributor specified Bronchi-Shield III - Pfizer SRL Protech Bronchi-shield III - Boehringer Ingelheim Animal Health Australia Pty. Ltd. Protech Bronchi-shield III - No distributor specified
Date of Compilation Summary	March 27, 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	Canine Adenovirus Type 2
Study Purpose	To demonstrate effectiveness against Canine Adenovirus Type 2
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	November 27, 1995

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

Study Type	Efficacy
Pertaining to	Canine Parainfluenza
Study Purpose	To demonstrate effectiveness against Canine Parainfluenza
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	November 27, 1995

Study Type	Safety
Pertaining to	Canine Adenovirus Type-2 (CAV-2)
Study Purpose	Development of corneal opacity is not associated with the use of this product
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data are not available.

<table>
<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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