



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
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 - No distributor specified Bronchi-Shield III - Zoetis Inc. - Elanco US Inc. Bronchi-Shield III - Zoetis Industria Produtos Veterinarios Ltda. - Elanco US Inc. Elanco US Inc. Protech Bronchi-shield III - Zoetis New Zealand Ltd - Elanco US Inc.
Date of Compilation Summary	September 16, 2019

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 (CAV2)
Study Purpose	To Demonstrate effectiveness against Canine Adenovirus Type 2
Product Administration	One dose was administered intranasally
Study Animals	Thirty-five (35) 3 week old puppies. Puppies were allocated into one control group of 13 placebo-vaccinated puppies (Controls), one vaccinate group of 6 puppies (Vaccine #1) and second group of vaccinates of 16 puppies (Vaccine #2). Both Vaccine #1 and #2 contained the same antigen level of CAV2. The difference between the vaccines was antigen level of <i>Bordetella bronchiseptica</i> with Vaccine #1 having a low titer and Vaccine #2 having a high titer.
Challenge Description	Eleven to 12 weeks after vaccination all puppies were challenged with virulent Canine Adenovirus Type 2.
Interval observed after challenge	Puppies were monitored daily for 2 weeks after challenge for presence of clinical signs.
Results	<p>The study was considered satisfactory by the reduction in clinical signs and virus shedding in the vaccinates when compared to the control animals.</p> <p>Raw Data: Data tables are appended to the end of the summary.</p>
USDA Approval Date	November 27, 1995

Clinical Signs Specific to CAV2 on Indicated Day after Challenge

Controls															
Dog ID	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1	0	0	0	SND	POD,V,D	SND,POD	POD	0	0	0	0	0	0	0	0
2	0	0	0	0	SND,POD	POD	POD	POD	0	0	0	0	0	0	0
3	0	0	0	0	POD,V	POD	POD	POD	0	0	0	0	0	0	0
4	0	0	0	0	POD,V,D	0	SND,POD,C	POD,C	0	0	0	0	0	0	0
5	PN D	0	0	POD	POD	PND,POD	SND,POD	POD	0	0	0	0	0	0	0
6	0	0	0	0	POD,C,V	POD	SND,POD,C	POD	POD	0	0	0	0	0	0
7	0	0	0	0	V	0	SND,POD	POD	0	0	0	0	0	0	0
8	0	0	0	0	0	POD	POD	POD	0	0	0	0	0	0	0
9	0	0	0	0	POD,D	POD	SND,POD	POD	POD	0	0	0	0	0	0
10	0	0	0	0	POD,D	POD	SND	POD	POD	0	POD	0	0	0	PND
11	0	0	0	SND	POD	0	POD	POD	0	0	0	0	0	0	0
12	0	0	0	SND	POD,V	PND,POD	SND,POD	0	POD	0	0	0	0	0	0
13	0	0	0	0	POD,V	POD	POD	0	0	0	0	0	0	0	SND

Vaccine #1															
Dog ID	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1	0	0	0	0	0	POD	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	NA	0	0	POD	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	PND	0	0	0	0	0	0	POD	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Vaccine #2															
Dog ID	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
7	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
9	0	0	0	0	POD	0	POD	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	POD	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	SND	0	POD	0	PND	PO D	0	0	0
15	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
22	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

0=normal SND=Serous Nasal discharge POD = Purulent ocular discharge
 V = Vomiting PND=purulent Nasal discharge C = Cough D = Diarrhea

CAV2 Virus Titer (Log10 FAID 50/mL) in Nasal Secretions on Indicated Days Post Challenge

Controls															
Dog ID	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1	<1.5	≤1.83	<1.5	3.8	≥5.5	3.5	2.8	≤1.83	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
2	<1.5	≥2.5	2.6	4.5	4.2	3.4	3.8	2.3	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
3	<1.5	<1.5	<1.5	4.8	4.6	≥5.0	4.5	≤1.63	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
4	<1.5	2.3	≤1.83	2.8	4.8	3.5	4.2	2.4	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
5	<1.5	2.4	2.6	3.3	4.6	3.5	3.4	2.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
6	<1.5	<1.5	≤1.63	3.8	4.4	2.8	3.4	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
7	<1.5	<1.5	≤1.63	2.3	3.6	2.0	3.6	≤1.83	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
8	<1.5	<1.5	≤1.63	3.6	≥5.0	3.6	3.3	≤1.83	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
9	<1.5	2.8	2.4	4.5	4.8	4.5	4.6	3.6	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
10	<1.5	≤1.63	≤1.83	3.0	≥5.0	3.6	3.6	3.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
11	<1.5	<1.5	≤1.83	3.4	≥5.0	4.6	4.8	3.2	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
12	<1.5	<1.5	<1.5	3.8	≥5.0	3.8	4.5	3.2	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
13	<1.5	<1.5	≤1.63	2.8	4.6	3.6	2.2	≤1.83	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5

Vaccine #1															
Dog ID	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
2	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
3	<1.5	<1.5	<1.5	2.2	≤1.63	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
4	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
6	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5

Vaccine #2															
Dog ID	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
7	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
8	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
9	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
10	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
11	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
12	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
13	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
14	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
15	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
16	<1.5	<1.5	<1.5	<1.5	≤1.83	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
17	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
18	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
19	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
20	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
21	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
22	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5

Study Type	Efficacy
Pertaining to	Bordetella Bronchiseptica
Study Purpose	To demonstrate effectiveness against <i>Bordetella bronchispetica</i> (Kennel Cough) in 3 week old puppies.
Product Administration	One dose was administered intranasally
Study Animals	Twenty nine 3 week old puppies, negative for <i>B. bronchiseptica</i> on throat swab. Puppies were allocated into one group of 16 vaccinated puppies and one control group of 13 placebo-vaccinated puppies.
Challenge Description	Six to Seven weeks after vaccination animals were challenged with virulent Bordetella Bronchispetica.
Interval observed after challenge	Puppies were monitored for 2 weeks after challenge for presence of coughing.
Results	<p>Puppies who were observed with a cough were considered to be affected by the challenge.</p> <p>Number affected: Vaccinates: 0/16 Controls: 13/13</p> <p>Raw data: A data table is appended to the end of this summary.</p>
USDA Approval Date	June 16, 1994

Dog ID	Cough observed on the indicated Days After Challenge In Control Puppies														
	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1					C	C		C							
2					C	C	C								
3					C	C	C	C	C	C					
4					C	C	C	C	C	C					
5					C	C	C	C	C	C					
6					C	C	C	C	C						
7					C	C	C	C	C						
8							C	C							
9					C	C	C	C	C						
10					C	C	C		C						
11					C	C	C	C							
12							C	C							
13					C										

C = Cough

There was no Coughing observed in the vaccinated treatment group.

Study Type	Efficacy
Pertaining to	Canine Parainfluenza Virus (CPI)
Study Purpose	To demonstrate effectiveness against Canine Parainfluenza Virus
Product Administration	One dose was administered intranasally
Study Animals	Thirty-one (31) 8-10 week old puppies negative for CPI. Puppies were allocated into one group of 22 vaccinated puppies and one control group of 9 puppies.
Challenge Description	Three weeks after vaccination all dogs were challenged with virulent Canine parainfluenza virus.
Interval observed after challenge	Puppies were monitored for 2 weeks after challenge for presence of clinical signs.
Results	<p>Vaccinates and Controls were evaluated per the criteria in 9 CFR 113.316 (b)(3)(4)</p> <ol style="list-style-type: none"> 1. No vaccinates were observed with respiratory or specific CPI clinical signs 2. No vaccinates showed a febrile response 3. All vaccinates demonstrated serum titers >4 after vaccination 4. A reduction in virus isolation rate in vaccinates when compared to controls was observed <p>Requirements of 9 CFR 113.316 (b)(3)& (4) were met.</p> <p>Raw data: Data tables are appended to the end of this summary.</p>
USDA Approval Date	November 27, 1995

Temperature in °F on Indicated Day Post Challenge

Controls															
Day Postchallenge															
Dog ID	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1	101.8	102.3	102.4	102.7	102.3	102.4	102.5	102.3	101.8	102.3	102.5	102.6	102.7	102.0	101.9
2	101.8	102.0	102.0	102.5	102.1	102.5	102.7	102.6	102.0	102.6	102.0	102.4	102.9	102.3	102.2
3	102.1	101.8	102.7	101.4	102.2	102.1	102.4	101.7	102.5	102.4	102.5	102.7	103.0	102.0	102.4
4	102.9	102.3	102.6	102.5	102.1	102.3	102.5	102.7	102.0	102.6	102.4	102.8	102.8	102.4	102.8
5	102.7	102.2	102.1	102.2	102.8	102.6	102.7	102.6	102.4	103.3	101.9	102.1	102.7	101.7	102.7
6	102.3	102.2	102.4	102.5	101.7	102.9	102.4	102.1	102.4	102.6	102.0	102.0	102.9	101.9	102.1
7	102.0	101.8	101.9	102.3	101.7	101.7	101.9	101.5	101.5	102.6	102.0	102.4	102.5	101.8	102.0
8	101.6	101.3	103.4	102.8	102.4	102.2	102.2	101.7	101.7	103.1	101.0	102.2	102.6	101.9	101.4
9	102.8	102.3	102.4	102.8	102.1	102.9	102.7	102.5	102.3	103.1	101.5	102.2	102.9	101.8	101.9

Vaccinates															
Day Postchallenge															
Dog ID	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1	102.1	101.8	102.3	102.1	102.2	102.1	102.3	102.4	102.0	102.2	102.3	102.7	102.1	101.7	102.0
2	101.8	101.9	102.4	101.3	100.0	102.1	101.9	101.9	101.6	102.1	102.0	102.3	102.3	101.5	101.8
3	101.9	101.3	102.0	101.3	102.2	102.1	101.6	101.4	101.4	102.1	101.0	102.0	101.8	101.5	101.2
4	101.9	101.8	102.1	101.8	101.9	102.2	102.1	102.1	101.6	102.3	102.5	103.2	101.7	102.6	101.9
5	101.6	101.5	102.2	101.5	102.2	101.7	101.7	101.7	102.0	101.8	102.6	102.9	102.0	101.5	101.8
6	102.4	101.8	102.0	102.6	101.3	101.9	102.4	102.4	102.6	102.1	102.5	102.5	102.3	101.9	102.1
7	102.1	100.9	101.6	101.4	100.4	101.4	102.0	101.2	101.1	101.7	101.8	101.4	101.6	102.0	101.7
8	101.8	102.1	102.3	102.3	102.1	101.8	102.3	102.4	102.3	102.2	102.0	102.5	102.0	101.8	102.0
9	101.8	101.8	101.6	101.8	101.6	101.5	101.7	101.3	101.1	102.0	101.8	101.6	102.1	101.5	101.6
10	101.5	102.3	102.4	101.9	101.4	102.5	102.4	102.1	102.5	102.2	101.8	103.1	101.9	102.5	101.9
11	101.7	101.6	101.4	101.6	100.3	101.7	101.8	101.8	101.4	102.0	102.1	101.6	101.9	101.6	101.5
12	100.5	101.7	102.1	101.8	101.3	102.0	101.8	102.3	102.2	101.8	102.1	102.2	101.5	102.1	101.5
13	102.7	102.0	101.9	102.4	101.4	102.4	102.0	101.6	102.2	102.3	102.1	102.8	101.8	102.2	102.1
14	101.6	102.3	102.1	101.4	102.0	102.2	102.5	101.8	102.0	102.5	103.0	102.4	102.0	102.2	102.3
15	102.1	102.3	102.8	102.7	102.2	102.2	102.5	102.4	101.6	103.3	102.0	102.8	102.9	103.0	102.9
16	101.9	101.5	101.9	101.4	101.3	102.5	101.7	101.7	101.5	102.1	102.3	102.4	102.0	101.9	101.6
17	102.6	102.1	101.9	102.4	102.0	102.3	102.1	101.8	101.9	102.7	102.9	102.6	102.6	102.2	101.8
18	101.5	102.3	102.0	101.5	101.2	102.2	102.3	102.0	102.5	102.6	102.6	102.4	102.4	101.8	101.9
19	102.3	102.6	102.8	102.5	102.4	102.3	101.9	102.7	101.1	102.8	102.8	102.4	102.8	101.9	102.0
20	102.4	101.9	101.8	102.3	101.7	102.3	102.2	101.7	102.4	102.5	102.7	102.8	101.8	101.7	101.9
21	102.0	101.8	101.9	102.4	102.3	102.1	102.0	101.9	101.4	102.7	102.1	102.2	102.3	102.4	101.4
22	102.6	102.4	102.5	102.6	102.2	102.4	102.4	101.8	102.4	102.7	102.0	102.5	102.7	102.0	102.6

Clinical Signs Observed on Indicated Days After Challenge

Controls																
Day Postchallenge																
Dog ID	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
5	0	0	0	0	0	0	0	0	0	SND	0	0	0	0	0	
6	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	SND	0	
8	0	0	0	0	0	0	0	0	0	SND	0	0	0	0	0	
9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

Vaccinates																
Day Postchallenge																
Dog ID	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
6	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	
8	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	
10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
11	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
12	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
13	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
14	0	0	0	0	0	0	0	0	0	0	0	V	0	0	0	
15	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
16	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
17	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
18	0	0	0	0	0	0	0	0	0	0	0	V	0	0	0	
19	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
20	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
21	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
22	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

0=normal SND=Serous Nasal discharge V = Vomiting

CPI Virus Titer (Log₁₀ FAID 50/mL) in Nasal Secretions on Indicated Days Post Challenge

Controls															
Day Postchallenge															
Dog ID	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1	N	2.6	3.0	2.6	N	N	N	N	N	N	N	N	N	N	N
2	N	N	2.5	2.3	≤1.8	≤1.8	N	N	N	N	N	N	N	N	N
3	N	≤1.6	2.6	2.5	3.0	2.2	N	N	N	N	N	N	N	N	N
4	N	2.6	3.3	≤1.6	N	N	N	N	N	N	N	N	N	N	N
5	N	2.8	4.0	N	N	N	N	N	N	N	N	N	N	N	N
6	N	2.4	2.8	2.0	≤1.8	≤1.8	2.0	N	N	N	N	N	N	N	N
7	N	N	3.0	≤1.8	2.2	≤1.6	≤1.6	N	N	N	N	N	N	N	N
8	N	N	3.3	2.5	≤1.6	N	≤1.6	N	N	N	N	N	N	N	N
9	N	2.9	3.5	3.5	2.8	N	N	N	N	N	N	N	N	N	N

N=no virus detected

*No virus was detected from nasal secretions in the vaccinated group on any day post challenge

Serum Neutralization Antibody Titer For CPI

Controls						
Dog ID	0DPV1	7DPV1	14DPV1	0DPC	7DPC	14DPC
1	<2	<2	<2	<2	<4	50
2	<2	<2	<2	<2	<4	32
3	<2	<2	<2	<2	<4	38
4	<2	<2	<2	<2	<4	64
5	<2	<2	<2	<2	<4	64
6	<2	<2	<2	<2	<4	50
7	<2	<2	<2	<2	<4	38
8	<2	<2	<2	<2	<4	50
9	<2	<2	<2	<2	<4	128

Vaccinates						
Dog ID	0DPV1	7DPV1	14DPV1	0DPC	7DPC	14DPC
1	<2	<4	32	128	153	153
2	<2	<4	20	50	108	128
3	<2	<4	108	108	324	128
4	<2	<4	50	128	128	201
5	<2	<4	32	128	153	128
6	<2	<4	27	108	324	324
7	<2	<4	32	108	128	81
8	<2	<4	50	108	153	153
9	<2	<4	108	128	201	324
10	<2	<4	20	50	128	128
11	<2	<4	20	32	128	256
12	<2	<4	<4	16	128	128
13	<2	<4	81	128	128	128
14	<2	<4	81	108	128	108
15	<2	<4	81	128	164	159
16	<2	<4	10	41	201	324
17	<2	<4	32	128	324	153
18	<2	<4	20	81	433	324
19	<2	<4	50	108	153	128
20	<2	<4	25	47	38	38
21	<2	<4	81	128	128	128
22	<2	<4	108	108	324	201

DPV1=day postvaccination
DPC=day postchallenge

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.

Study Type	Safety																								
Pertaining to	ALL																								
Study Purpose	Demonstrate safety of product under typical use conditions																								
Product Administration	Each animal was given 1 dose intranasally, by inoculating 1/2 dose into each nostril.																								
Study Animals	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.																								
Challenge Description	NA																								
Interval observed after challenge	Animals were observed for 1 hour after vaccination and daily for two weeks after vaccination.																								
Results	<p>Frequency of adverse events:</p> <table border="1"> <thead> <tr> <th></th> <th>Number of Animals</th> <th>Percent of Animals</th> </tr> </thead> <tbody> <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> </tbody> </table> <p>*Affirmed by study investigator to have cause other than vaccination</p>		Number of Animals	Percent of Animals	No Adverse Events	675	96.98%	Lethargy	3	0.43%	Anorexia	1	0.14%	Sneezing	5	0.72%	Cough	10	1.44%	Rhinitis	7	1.01%	Death	3*	0.43%
	Number of Animals	Percent of Animals																							
No Adverse Events	675	96.98%																							
Lethargy	3	0.43%																							
Anorexia	1	0.14%																							
Sneezing	5	0.72%																							
Cough	10	1.44%																							
Rhinitis	7	1.01%																							
Death	3*	0.43%																							
USDA Approval Date	February 5, 1996																								