



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	15Q5.20
True Name	Canine Influenza Vaccine, H3N2 & H3N8, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Vanguard CIV H3N2/H3N8 - No distributor specified
Date of Compilation Summary	July 26, 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	Canine Influenza Virus (CIV), H3N2																					
Study Purpose	To demonstrate effectiveness against canine influenza virus, H3N2																					
Product Administration	Two doses, administered subcutaneously, 3 weeks apart.																					
Study Animals	Study involved 20 vaccinated and 20 placebo puppies, 7-8 weeks of age.																					
Challenge Description	Challenged with CIV H3N2, 14 days following administration of the second vaccination.																					
Interval observed after challenge	After challenge, animals were observed twice daily for clinical signs of respiratory disease (moderate nasal discharge, coughing, sneezing, depression, retching, labored breathing, fever (≥ 39.5 °C)) for 6 days. Lungs were evaluated at 6 days post-challenge.																					
Results	<p>Efficacy was based on discrete lung lesions.</p> <p>Table 1: Five number summary of lung lesion scores by treatment group. Percentage of lung mass abnormal (consolidated) was calculated for every animal ($Q_1 = 25^{\text{th}}$ percentile; $Q_3 = 75^{\text{th}}$ percentile).</p> <table border="1"> <thead> <tr> <th></th> <th>N</th> <th>Minimum</th> <th>Q_1</th> <th>Median</th> <th>Q_3</th> <th>Maximum</th> </tr> </thead> <tbody> <tr> <td>Vaccinate</td> <td>17</td> <td>0.0</td> <td>0.0</td> <td>0.0</td> <td>0.0</td> <td>0.9</td> </tr> <tr> <td>Control</td> <td>20</td> <td>0.7</td> <td>5.2</td> <td>10.4</td> <td>20.4</td> <td>38.4</td> </tr> </tbody> </table> <p>Note: Three dogs (within the vaccinate group) were removed from the lesion score because of atelectasis at lung examination.</p> <p>The supporting clinical signs and pathological lung lesion data were shown to be complementary. For an animal to be considered as diseased, two or more clinical signs were required to be present on 2 or more consecutive days.</p> <p>17/20 control animals were affected 0/20 vaccinated animals were affected</p> <p>The raw data are shown on attached page.</p>		N	Minimum	Q_1	Median	Q_3	Maximum	Vaccinate	17	0.0	0.0	0.0	0.0	0.9	Control	20	0.7	5.2	10.4	20.4	38.4
	N	Minimum	Q_1	Median	Q_3	Maximum																
Vaccinate	17	0.0	0.0	0.0	0.0	0.9																
Control	20	0.7	5.2	10.4	20.4	38.4																
USDA Approval Date	January 11, 2017																					

Table 2: Individual animal raw data for lung consolidation (lesions)

Treatment	Animal	Percent Consolidation
Control	CDI-6	1.17
	ZTI-6	7.79
	DEJ-6	11.95
	DFJ-6	19.92
	ZRJ-6	20.45
	CFJ-6	4.86
	ALJ-6	0.72
	CUJ-6	23.41
	CII-6	23.52
	CVI-6	6.55
	DJI-6	5.39
	ADI-6	6.44
	CGJ-6	29.37
	BRJ-6	19.91
	ZYI-6	1.03
	BOJ-6	20.41
	APJ-6	5.10
	CTJ-6	8.80
	ACI-6	16.43
	AOJ-6	38.42

Treatment	Animal	Percent Consolidation
Vaccinates	CCI-6	0.00
	ZSI-6	0.00
	ZQJ-6	0.00
	CHI-6	0.00
	ARI-6	0.00
	CXI-6	0.00
	BYI-6	0.00
	DII-6	0.00
	ABJ-6	0.21
	CJI-6	0.00
	AAJ-6	0.87
	ZZI-6	0.21
	BPJ-6	0.92
	AKJ-6	0.00
	CWI-6	0.00
	AEI-6	0.00
	AQI-6	0.00

Table 3: Individual animal raw data for coughing

Animal	Trt	Study Day 34		Study Day 35		Study Day 36		Study Day 37		Study Day 38		Study Day 39		Study Day 40		Study Day 41
		AM	PM	Pre-Chall	Post-Chall	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM
ACI-6	Control Animals	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0
ADI-6		0	0	0	0	0	0	0	2	0	0	2	2	0	0	0
ALJ-6		0	0	0	0	2	2	0	2	2	2	3	2	2	2	2
AOJ-6		0	0	0	0	0	2	2	2	0	0	0	2	0	2	0
APJ-6		0	0	0	0	2	0	2	2	2	2	0	0	0	2	2
BOJ-6		0	0	0	0	0	1	0	0	0	0	2	0	2	2	0
BRJ-6		0	0	0	0	0	0	0	0	2	2	0	2	2	0	0
CDI-6		0	0	0	0	0	2	0	0	0	0	0	2	0	2	0
CFJ-6		0	0	0	0	0	0	0	0	0	2	0	2	2	0	0
CGJ-6		0	0	0	0	2	0									
CII-6		0	0	0	0	0	0	0	0	0	2	3	3	3	0	3
CTJ-6		0	0	0	0	0	0	0	0	2	2	2	0	2	2	0
CUJ-6		0	0	0	0	2	0	0	0	2	0	3	0	0	0	1
CVI-6		0	0	0	0	0	2	0	2	0	2	0	2	2	2	2
DEJ-6		0	0	0	0	0	0	1	0	2	0	2	2	2	0	0
DFJ-6		0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
DJI-6		0	0	0	0	0	2	0	1	0	0	0	2	2	2	2
ZRJ-6		0	0	0	0	0	2	0	0	2	0	0	0	0	0	0
ZTI-6		0	0	0	0	0	0	0	0	2	0	2	1	2	2	0
ZYI-6		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
AAJ-6	Vaccinated Animals	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0
ABJ-6		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
AEI-6		0	0	0	0	0	0	0	0	2	0	0	0	0	0	2
AKJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AQI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ARI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BPJ-6		0	0	0	0	0	0	2	0	0	0	0	0	0	0	0
BYI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CCI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CEJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CHI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CJI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CWI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CXI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DGJ-6		0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
DHJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DII-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ZQJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ZSI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ZZI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Cough:

0 – Absent

1 – Mild: Animal coughed once during clinical observation

2 – Moderate: Spontaneous/frequent coughing. Animal coughed 2X or more during clinical observation.

3 – Severe: Spontaneous with retching/Frequent coughing with retching. Animal had persistent and prolonged cough.

Table 4: Individual animal raw data for fever ($\geq 39.5^{\circ}\text{C}$)

Animal	Trt	Study Day 34	Study Day 35 Pre-Chall	Study Day 35 Post-Chall	Study Day 36	Study Day 37	Study Day 38	Study Day 39	Study Day 40	Study Day 41
ACI-6	Control Animals	38.4	38	37.4	39.2	38	38.1	38.9	38.1	38.2
ADI-6		38.4	38.5	37.8	38.9	38.2	39.7	39	37.6	38.1
ALJ-6		39	39	38.8	39.7	38.9	39.8	40.4	39	38.8
AOJ-6		38.6	38.3	38.4	38.6	38.5	39	38.6	38.8	38.7
APJ-6		38.9	37.8	38.7	38.6	37.6	39.3	39.3	38.6	38.7
BOJ-6		38.4	37.5	38	39	38.1	38.9	39.7	38.2	37.7
BRJ-6		38.7	38.4	37.1	39.3	38.8	39.9	38.6	37.8	37.8
CDI-6		39.2	38.8	38.8	40.2	38.7	38.7	39.4	38.5	38.7
CFJ-6		39.1	38.1	38.6	39.3	38.5	39	38.8	38.1	38.7
CGJ-6		39.1	38	37.8	37.5					
CII-6		39.3	38.8	39	40.1	39.1	38.9	39.5	38.9	39
CTJ-6		38.9	38.1	37.7	39.6	38.7	38.5	38.9	37.8	37.8
CUJ-6		39.1	38.6	38.4	39.9	38.9	40.1	40.5	38.6	38.7
CVI-6		39	38.4	38.7	40.4	39	39	38.7	38.5	38.8
DEJ-6		38.8	38.8	38.8	39.8	38.9	39	39.6	38.8	39
DFJ-6		39.2	39.3	39.1	40.2	39.3	39.2	39.1	38.8	39.1
DJI-6		38.8	38.5	38.5	39.5	38.4	38.4	38.9	38.5	38.7
ZRJ-6		38.1	38.5	38.6	39.4	39.1	40.2	39.1	38.7	38.8
ZTI-6		39.2	39.1	38.4	39.5	39.2	39.3	38.9	39.2	39.2
ZYI-6		38.6	38.2	37.8	39	38.2	38.5	38.5	37.7	37.7
AAJ-6	Vaccinated Animals	38.9	38.9	37.7	38.2	37.7	38.1	38.8	38.7	38.5
ABJ-6		38.6	37.9	37.8	38.2	37.9	38.6	38.4	37.5	38.3
AEI-6		38.5	37.9	37.9	37.5	37.8	38	38	38.1	38.1
AKJ-6		38.7	38.2	38.5	38.2	37.7	38.7	38.3	38.4	38.3
AQI-6		38.5	38.4	38.4	37.8	38.4	38	38.4	38.6	38.2
ARI-6		38.7	38.4	38.7	38	38.9	38.9	39.1	38.7	38.7
BPJ-6		38.3	38	38.1	38	38	38	38.2	37.9	38.4
BYI-6		38.9	38.7	38.7	38.1	39	38.2	38.6	38.5	38.5
CCI-6		39.2	38.9	38.7	38.4	39.6	38.6	39.1	38.6	38.9
CEJ-6		39	38.7	39	39.1	38.8	38.5	38.7	38	39.1
CHI-6		38.9	38.8	38.3	38.8	38.6	38.9	39.1	38.5	39.2
CJI-6		38.6	38.2	37.8	38.3	37.9	38	39.1	38.4	38.3
CWI-6		38.1	37.9	37.8	37.8	38.4	38.7	37.9	38.3	38.1
CXI-6		39	38.1	38.8	38.2	38.8	38.8	39.2	39	38.8
DGJ-6		38.2	39	38.9	38.3	39	38.6	38.6	38.6	38.7
DHJ-6		39	38.7	38	38.6	38.3	38.4	38.4	38.2	38.9
DII-6		38.8	38.7	38.5	38.2	38.1	38.4	38.3	38.4	38.8
ZQJ-6		38.9	39.3	38.6	38.6	39.6	39.3	39.1	38.8	38.7
ZSI-6		39.4	39	38.9	39.1	39.4	38.8	38.9	38.9	38
ZZI-6		38.6	38.4	37.4	37.8	38.4	38.5	38.2	37.9	38.1

Table 5: Individual animal raw data for depression

Animal	Trt	Study Day 34		Study Day 35		Study Day 36		Study Day 37		Study Day 38		Study Day 39		Study Day 40		Study Day 41
		AM	PM	Pre-Chall	Post-Chall	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM
ACI-6	Control Animals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ADI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ALJ-6		0	0	0	0	0	0	0	0	0	1	0	1	0	0	0
AOJ-6		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
APJ-6		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
BOJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BRJ-6		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
CDI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CFJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CGJ-6		0	0	0	0	0	0	1								
CII-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CTJ-6		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
CUJ-6		0	0	0	0	0	1	0	0	0	2	0	2	0	0	0
CVI-6		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
DEJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DFJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DJI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ZRJ-6		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
ZTI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ZYI-6		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
AAJ-6	Vaccinated Animals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AEI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AKJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AQI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ARI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BPJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BYI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CCI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CEJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CHI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CJI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CWI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CXI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DGJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DHJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DII-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ZQJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ZSI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ZZI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Depression:

0 – Absent

1 – Mild: Animal is slow to rise, lost interest in playing but still somewhat active

2 – Moderate: Animal is able to rise and move, but inactive other than to eat or drink

3 – Severe: Animal is recumbent, unable to rise, and refuses food and/or drink

Table 6: Individual animal raw data for nasal discharge

Animal	Trt	Study Day 34		Study Day 35		Study Day 36		Study Day 37		Study Day 38		Study Day 39		Study Day 40		Study Day 41
		AM	PM	Pre-Chall	Post-Chall	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM
ACI-6	Control Animals	0	0	0	0	0	0	0	0	2	1	2	0	2	0	2
ADI-6		0	0	0	0	1	0	0	1	2	0	1	1	1	0	0
ALJ-6		0	0	0	0	1	0	0	2	2	2	2	2	2	0	0
AOJ-6		0	0	2	2	2	2	2	1	2	0	2	0	0	0	2
APJ-6		0	0	0	0	1	1	1	0	2	1	1	0	0	1	1
BOJ-6		0	0	0	0	0	0	0	1	2	1	3	0	1	2	0
BRJ-6		0	0	0	0	1	0	2	2	3	1	2	2	1	1	2
CDI-6		0	0	0	0	1	1	0	0	1	2	1	1	0	0	2
CFJ-6		0	0	0	0	0	0	0	0	1	2	1	0	0	0	2
CGJ-6		0	0	0	0	2	0									
CII-6		0	0	0	0	1	2	0	0	1	1	2	1	2	0	2
CTJ-6		0	0	0	0	0	0	0	0	3	2	3	0	2	0	0
CUJ-6		0	0	0	0	0	0	0	0	3	2	3	2	3	0	0
CVI-6		0	0	0	0	0	0	0	0	2	1	2	1	0	2	1
DEJ-6		0	0	0	0	1	2	0	1	3	2	3	0	1	0	0
DFJ-6		0	0	0	0	0	0	0	0	1	0	1	1	0	0	0
DJI-6		0	0	0	0	0	1	1	0	0	0	1	0	0	0	0
ZRJ-6		0	0	0	0	1	0	1	0	2	0	1	2	0	0	0
ZTI-6		0	0	1	0	1	0	0	1	1	2	1	2	1	0	1
ZYI-6		0	0	0	0	1	0	0	0	3	2	2	1	0	0	2
AAJ-6	Vaccinated Animals	0	0	0	1	0	2	0	0	1	0	1	0	0	0	0
ABJ-6		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AEI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AKJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AQI-6		1	0	1	0	0	0	0	0	1	0	1	0	1	0	0
ARI-6		0	0	0	0	0	1	1	0	0	0	1	0	0	0	2
BPJ-6		0	0	0	0	0	0	0	0	1	0	1	0	0	0	0
BYI-6		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CCI-6		0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
CEJ-6		0	0	0	0	0	0	0	0	1	0	1	0	0	0	0
CHI-6		0	0	1	0	0	0	0	0	0	0	1	0	0	0	1
CJI-6		1	0	0	0	0	0	0	0	1	0	2	0	0	0	0
CWI-6		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
CXI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DGJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DHJ-6		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DII-6		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
ZQJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ZSI-6		0	0	0	0	0	0	0	0	1	0	1	0	0	0	0
ZZI-6		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0

Nasal Discharge:

0 – Absent (includes normal, moist nose)

1 – Mild: Serous (clear, watery) discharge, must be extending approximately ½ way down the nasal philtrim

2 – Moderate: Serous extending more than ½ way down the nasal philtrim, or evidence of mucopurulent discharge

3 – Severe: Mucopurulent discharge extending more than ½ way down the nasal philtrim, or bloody, or a combination of mucopurulent and bloody discharge

Table 7: Individual animal raw data for labored breathing

Animal	Trt	Study Day 34		Study Day 35		Study Day 36		Study Day 37		Study Day 38		Study Day 39		Study Day 40		Study Day 41
		AM	PM	Pre-Chall	Post-Chall	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM
ACI-6	Control Animals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ADI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ALJ-6		0	0	0	0	0	0	0	0	0	0	2	0	0	0	0
AOJ-6		0	0	0	0	3	0	0	0	0	0	0	0	0	0	0
APJ-6		0	0	0	0	0	0	0	2	2	0	0	0	0	0	2
BOJ-6		0	0	0	0	0	0	0	0	0	0	2	0	0	0	0
BRJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CDI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	2	0
CFJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CGJ-6		0	0	0	0	3	3									
CII-6		0	0	0	0	2	3	2	0	0	2	2	0	0	0	0
CTJ-6		0	0	0	0	2	2	0	0	2	0	0	0	0	0	0
CUJ-6		0	0	0	0	0	0	0	0	0	0	2	0	0	0	0
CVI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEJ-6		0	0	0	0	0	0	0	0	2	0	0	0	0	0	0
DFJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DJI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ZRJ-6		0	0	0	0	0	0	0	0	2	0	0	0	0	0	0
ZTI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
ZYI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AAJ-6	Vaccinated Animals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AEI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AKJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AQI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ARI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BPJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BYI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CCI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CEJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CHI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CJI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CWI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CXI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DGJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DHJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DII-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ZQJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ZSI-6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ZZI-6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

Labored breathing:

0 – Absent

2 – Moderate: Small clicking, bubbling, or rattling sounds in the lung (Rales)

3 – Severe: Difficult or labored breathing; shortness of breath (Dyspnea)

Table 8: Individual animal raw data for retching

Animal	Trt	Study Day 34		Study Day 35		Study Day 36		Study Day 37		Study Day 38		Study Day 39		Study Day 40		Study Day 41
		AM	PM	Pre-Chall	Post-Chall	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM
ACI-6	Control Animals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ADI-6		0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
ALJ-6		0	0	0	0	1	0	0	1	1	0	1	1	2	0	0
AOJ-6		0	0	0	0	2	0	1	0	0	0	0	0	0	1	0
APJ-6		0	0	0	0	2	0	1	1	1	1	0	0	0	0	0
BOJ-6		0	0	0	0	0	0	0	0	0	0	2	0	0	0	0
BRJ-6		0	0	0	0	0	0	0	0	0	1	0	1	0	0	0
CDI-6		0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
CFJ-6		0	0	0	0	0	0	0	0	0	1	0	2	1	0	0
CGJ-6		0	0	0	0	1	2									
CII-6		0	0	0	0	0	0	0	0	0	1	2	2	2	0	2
CTJ-6		0	0	0	0	0	3	0	0	0	0	0	0	0	0	0
CUJ-6		0	0	0	0	0	0	0	0	1	0	2	0	0	0	0
CVI-6		0	0	0	0	0	2	0	1	0	0	0	1	0	0	0
DEJ-6		0	0	0	0	0	0	0	0	1	0	0	2	0	0	0
DFJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DJI-6		0	0	0	0	0	2	0	0	0	0	0	2	0	2	0
ZRJ-6		0	0	0	0	0	2	0	0	1	0	0	0	0	0	0
ZTI-6		0	0	0	0	0	2	0	2	0	2	0	0	0	0	0
ZYI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AAJ-6	Vaccinated Animals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AEI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AKJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AQI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ARI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BPJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BYI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CCI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CEJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CHI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CJI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CWI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CXI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DGJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DHJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DII-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ZQJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ZSI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ZZI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Retching: incoercible and unsuccessful attempts to vomit

- 0 – Absent
- 1 – Mild: Animal retches or vomits once briefly or occasionally
- 2 – Moderate: Animal retches or vomits for a prolonged period
- 3 – Severe: Animal retches or vomits multiple times for a prolonged period

Table 9: Individual animal raw data for sneezing

Animal	Trt	Study Day 34		Study Day 35		Study Day 36		Study Day 37		Study Day 38		Study Day 39		Study Day 40		Study Day 41
		AM	PM	Pre-Chall	Post-Chall	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM
ACI-6	Control Animals	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
ADI-6		0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
ALJ-6		0	0	0	0	0	0	0	0	0	0	0	0	2	0	0
AOJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
APJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BOJ-6		2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BRJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
CDI-6		0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
CFJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CGJ-6		0	0	0	0	0	0	0								
CII-6		0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
CTJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CUJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CVI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DFJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DJI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ZRJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ZTI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ZYI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AAJ-6	Vaccinated Animals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AEI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AKJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AQI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ARI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BPJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BYI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CCI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CEJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CHI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CJI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CWI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CXI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DGJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DHJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DII-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ZQJ-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ZSI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ZZI-6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Sneezing:

- 0 – Absent
- 1 – Mild: Animal sneezed once or twice during observation
- 2 – Moderate: Animal sneezed repeatedly during clinical observation
- 3 – Severe: Animal presented paroxysmal sneeze

Study Type	Efficacy																																																	
Pertaining to	Canine Influenza Virus (CIV), H3N8																																																	
Study Purpose	To demonstrate effectiveness against canine influenza virus, H3N8																																																	
Product Administration	Two doses, administered subcutaneously, 3 weeks apart.																																																	
Study Animals	Study involved 24 vaccinated and 24 placebo puppies, 7-8 weeks of age.																																																	
Challenge Description	Challenged with CIV H3N8, 14 days following administration of the second vaccination.																																																	
Interval observed after challenge	After challenge, animals were observed daily for signs of clinical respiratory disease indicative of CIV, primarily cough. Lungs were evaluated in 4 randomly selected dogs per group 4 days after challenge. The remainder were evaluated 11 days after challenge.																																																	
Results	<p>Efficacy was based on clinical observations, lung consolidation, and post-challenge viral isolation from nasal swabs.</p> <p>Table 1: Summary of clinical observations, number and percentage of animals that ever had a positive observation for cough.</p> <table border="1"> <thead> <tr> <th rowspan="2">Treatment Group</th> <th colspan="2">Coughing</th> </tr> <tr> <th>Number</th> <th>%</th> </tr> </thead> <tbody> <tr> <td>Placebo</td> <td>13</td> <td>65</td> </tr> <tr> <td>Vaccinates</td> <td>2</td> <td>10</td> </tr> </tbody> </table> <p>The raw data are shown on the attached page.</p> <p>Table 2: Five number summary of lung lesion scores by treatment group for diffuse and discrete lung consolidation. Percentage of lung mass abnormal (consolidated) was calculated for every animal ($Q_1 = 25^{\text{th}}$ percentile; $Q_3 = 75^{\text{th}}$ percentile).</p> <table border="1"> <thead> <tr> <th>Type of Consolidation</th> <th>Treatment</th> <th>N</th> <th>Minimum</th> <th>Q1</th> <th>Median</th> <th>Q3</th> <th>Maximum</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Diffuse</td> <td>Placebo</td> <td>24</td> <td>0.00</td> <td>37.05</td> <td>80.13</td> <td>91.57</td> <td>100.00</td> </tr> <tr> <td>Vaccinates</td> <td>24</td> <td>0.00</td> <td>0.00</td> <td>17.13</td> <td>93.24</td> <td>100.00</td> </tr> <tr> <td rowspan="2">Discrete</td> <td>Placebo</td> <td>24</td> <td>0.00</td> <td>0.44</td> <td>1.72</td> <td>5.86</td> <td>32.05</td> </tr> <tr> <td>Vaccinates</td> <td>24</td> <td>0.00</td> <td>0.07</td> <td>0.28</td> <td>0.49</td> <td>5.00</td> </tr> </tbody> </table> <p>In addition, 24/24 placebo dogs and 4/24 vaccinated dogs had histopathologic evidence of damage to the respiratory epithelium. The raw data for the animals are shown on the attached page.</p>	Treatment Group	Coughing		Number	%	Placebo	13	65	Vaccinates	2	10	Type of Consolidation	Treatment	N	Minimum	Q1	Median	Q3	Maximum	Diffuse	Placebo	24	0.00	37.05	80.13	91.57	100.00	Vaccinates	24	0.00	0.00	17.13	93.24	100.00	Discrete	Placebo	24	0.00	0.44	1.72	5.86	32.05	Vaccinates	24	0.00	0.07	0.28	0.49	5.00
Treatment Group	Coughing																																																	
	Number	%																																																
Placebo	13	65																																																
Vaccinates	2	10																																																
Type of Consolidation	Treatment	N	Minimum	Q1	Median	Q3	Maximum																																											
Diffuse	Placebo	24	0.00	37.05	80.13	91.57	100.00																																											
	Vaccinates	24	0.00	0.00	17.13	93.24	100.00																																											
Discrete	Placebo	24	0.00	0.44	1.72	5.86	32.05																																											
	Vaccinates	24	0.00	0.07	0.28	0.49	5.00																																											

	<p>Table 3: Five number summary for number of days with positive H3N8 nasal pharyngeal swab virus isolation post-challenge (Q₁ = 25th percentile; Q₃ = 75th percentile).</p> <table border="1" data-bbox="507 472 1417 624"> <thead> <tr> <th>Treatment</th> <th>Minimum</th> <th>Q1</th> <th>Median</th> <th>Q3</th> <th>Maximum</th> </tr> </thead> <tbody> <tr> <td>Placebo</td> <td>4.00</td> <td>4.00</td> <td>5.00</td> <td>6.00</td> <td>7.00</td> </tr> <tr> <td>Vaccinates</td> <td>0.00</td> <td>0.00</td> <td>0.00</td> <td>1.00</td> <td>2.00</td> </tr> </tbody> </table> <p>The raw data for the animals are shown on the attached page.</p>	Treatment	Minimum	Q1	Median	Q3	Maximum	Placebo	4.00	4.00	5.00	6.00	7.00	Vaccinates	0.00	0.00	0.00	1.00	2.00
Treatment	Minimum	Q1	Median	Q3	Maximum														
Placebo	4.00	4.00	5.00	6.00	7.00														
Vaccinates	0.00	0.00	0.00	1.00	2.00														
USDA Approval Date	September 3, 2010																		

Table 4: Individual animal raw data for lung consolidation (% involvement)

			Type of Consolidation					Type of Consolidation	
Treatment	Final Evaluation Day Post-Challenge	Animal	Diffuse	Discrete	Treatment	Final Evaluation Day Post-Challenge	Animal	Diffuse	Discrete
Placebo	4	OZR-9	100.00	1.72	Vaccinates	4	PAR-9	42.30	0.50
		PKR-9	94.57	0.47			POQ-9	0.00	0.26
		QBQ-9	52.18	2.97			QCQ-9	1.41	0.47
		QER-9	84.08	1.05			QZQ-9	95.00	5.00
	11	OOR-9	0.80	8.13		11	OLR-9	98.28	0.07
		OPQ-9	92.41	0.00			OQR-9	1.19	0.00
		ORR-9	76.23	22.85			OSQ-9	82.49	0.20
		OTQ-9	90.29	1.17			OUQ-9	25.27	0.30
		PCQ-9	82.54	4.77			PBR-9	83.81	0.43
		PER-9	91.91	0.31			PDQ-9	0.00	0.20
		PHQ-9	77.73	0.09			PFQ-9	9.00	0.27
		PIQ-9	0.00	13.74			PGQ-9	0.00	0.00
		PLQ-9	91.22	2.07			PRR-9	0.00	0.00
		PPR-9	4.90	6.96			PSR-9	100.00	0.33
		PQQ-9	55.03	1.72			PTR-9	0.00	0.40
		PUR-9	0.00	0.30			PVR-9	0.00	0.07
		PWQ-9	44.62	1.68			PYR-9	1.19	0.15
		PXR-9	88.51	0.41			QDR-9	100.00	0.00
		PZR-9	17.47	3.75			QHR-9	0.00	0.00
		QFQ-9	75.74	8.78			QLQ-9	91.48	2.78
		QGR-9	89.83	3.42			QPR-9	95.23	0.50
		QKQ-9	95.46	0.00			QQR-9	88.15	0.50
		QTQ-9	98.31	1.08			QWR-9	0.00	0.40
		QXR-9	29.48	32.05			QYQ-9	97.62	2.56

Table 5: Individual animal raw data for coughing

Treatment	Final Evaluation Day Post-Challenge	Animal	Day of Study - Cough														
			32	33	34	35	36	37	38	39	40	41	42	43	44	45	46
Placebo	4	OZR-9	0	0	0	0	0	0	0	0	1						
		PKR-9	0	0	0	0	0	0	0	0	0						
		QBQ-9	0	0	0	0	0	0	0	0	0						
		QER-9	0	0	0	0	0	1	2	2							
	11	OOR-9	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
		OPQ-9	0	0	0	0	0	0	0	2	0	0	0	0	2	0	0
		ORR-9	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
		OTQ-9	0	0	0	0	0	2	2	2	2	1	2	1	1	2	0
		PCQ-9	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0
		PER-9	0	0	0	0	0	0	1	2	2	2	2	0	0	1	0
		PHQ-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		PIQ-9	0	0	0	0	0	0	1	2	2	1	1	1	1	1	0
		PLQ-9	0	0	0	0	0	2	2	1	0	2	2	1	0	0	0
		PPR-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		PQQ-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		PUR-9	0	0	0	0	0	0	2	1	0	1	0	0	2	0	0
		PWQ-9	0	0	0	0	0	0	1	1	1	1	1	0	0	0	0
		PXR-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		PZR-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		QFQ-9	0	0	0	0	0	0	0	0	1	1	0	1	1	0	0
		QGR-9	0	0	0	0	0	0	2	0	1	0	2	1	0	0	1
		QKQ-9	0	0	0	0	0	1	1	2	2	1	1	0	0	2	1
		QTQ-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
QXR-9		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Vaccinates	4	PAR-9	0	0	0	0	0	0	0	0							
		POQ-9	0	0	0	0	0	0	0	0							
		QCQ-9	0	0	0	0	0	0	0	0							
		QZQ-9	0	0	0	0	0	0	0	0							
	11	OLR-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		OQR-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		OSQ-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		OUQ-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		PBR-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		PDQ-9	0	0	0	0	0	0	0	0	1	0	0	0	0	0	
		PFQ-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		PGQ-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		PRR-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		PSR-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		PTR-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		PVR-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		PYR-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		QDR-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		QHR-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		QLQ-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		QPR-9	0	0	0	0	0	0	0	0	0	0	0	0	0	1	
		QQR-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		QWR-9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
QYQ-9		0	0	0	0	0	0	0	0	0	0	0	0	0	0		

0 = Absent
 1 = Mild: Animal coughed once during clinical observation
 2 = Moderate: Animal coughed 2x or more during clinical observation period
 3 = Severe: Animal had persistent and prolonged cough

Table 6: Individual animal raw data for the number of days with positive H3N8 virus isolation post-challenge

Treatment	Final Observation Day Post-Challenge	Animal	Number of Days Positive	Treatment	Final Observation Day Post-Challenge	Animal	Number of Days Positive
Placebo	4	OZR-9	4	Vaccinates	4	PAR-9	1
		PKR-9	4			POQ-9	0
		QBQ-9	4			QCQ-9	0
		QER-9	4			QZQ-9	0
	11	11	OOR-9		6	OLR-9	0
			OPQ-9		6	OQR-9	0
			ORR-9		7	OSQ-9	0
			OTQ-9		6	OUQ-9	2
			PCQ-9		6	PBR-9	1
			PER-9		4	PDQ-9	0
			PHQ-9		4	PFQ-9	0
			PIQ-9		6	PGQ-9	0
			PLQ-9		6	PRR-9	1
			PPR-9		6	PSR-9	1
			PQQ-9		5	PTR-9	0
			PUR-9		5	PVR-9	1
			PWQ-9		5	PYR-9	0
			PXR-9		5	QDR-9	0
			PZR-9		4	QHR-9	1
			QFQ-9		6	QLQ-9	0
			QGR-9		5	QPR-9	0
			QKQ-9		6	QQR-9	0
			QTQ-9		5	QWR-9	1
QXR-9	5	QYQ-9	0				

Table 7. Individual animal raw data for histopathologic damage to respiratory epithelium

Treatment	Final Observation Day Post-Challenge	Animal	Histopathologic Damage to Respiratory Epithelium	Treatment	Final Observation Day Post-Challenge	Animal	Histopathologic Damage to Respiratory Epithelium
Placebo	4	OZR-9	+	Vaccinates	4	PAR-9	-
		PKR-9	+			POQ-9	-
		QBQ-9	+			QCQ-9	-
		QER-9	+			QZQ-9	-
	OOR-9	-	OLR-9		-		
	OPQ-9	+	OQR-9		+		
	ORR-9	+	OSQ-9		+		
	OTQ-9	+	OUQ-9		-		
	PCQ-9	+	PBR-9		-		
	PER-9	+	PDQ-9		-		
	PHQ-9	+	PFQ-9		-		
	PIQ-9	+	PGQ-9		+		
	PLQ-9	+	PRR-9		+		
	PPR-9	+	PSR-9		-		
	PQQ-9	+	PTR-9		-		
	PUR-9	+	PVR-9		-		
	PWQ-9	+	PYR-9		-		
	PXR-9	+	QDR-9		-		
	PZR-9	+	QHR-9		-		
	QFQ-9	+	QLQ-9		-		
	QGR-9	+	QPR-9		-		
	QKQ-9	+	QQR-9		-		
	QTQ-9	+	QWR-9		-		
QXR-9	+	QYQ-9	-				

‘+’ denotes any degree of change to respiratory epithelium of the trachea, bronchi, and bronchioles.

‘-’ denotes no change to the respiratory epithelium of the trachea, bronchi, and bronchioles.

Study Type	Safety																				
Pertaining to	ALL																				
Study Purpose	To demonstrate safety under field conditions.																				
Product Administration	Two doses, administered subcutaneously, 3 weeks apart.																				
Study Animals	The study involved 364 dogs in total, with 118 dogs \leq 8 weeks of age and 246 dogs \geq 9 weeks of age from 15 sites in four different geographical locations. Three animals did not complete the study after the first vaccination. A total of 725 vaccinations were given.																				
Challenge Description	N/A.																				
Interval observed after challenge	<p>Immediate abnormal health events were assessed by the examining veterinarian or by a trained specialist for approximately 10-20 minutes post (each) vaccination.</p> <p>Dogs were observed for late abnormal health events primarily by their owners, or by Veterinarians or trained specialists. The observations were performed for 10 days post (each) vaccination.</p>																				
Results	<p>Table 1: Frequency Distributions of Immediate Reactions following Vaccination</p> <table border="1"> <thead> <tr> <th>Abnormal Health Events</th> <th>Total Number of Events</th> <th>% of Events</th> <th>Total Number Vaccinations</th> </tr> </thead> <tbody> <tr> <td>Injection Site Paraesthesia</td> <td>3</td> <td>0.4</td> <td>725</td> </tr> <tr> <td>Vocalization at Administration</td> <td>7</td> <td>1.0</td> <td>725</td> </tr> <tr> <td>Injection site Edema</td> <td>1</td> <td>0.1</td> <td>725</td> </tr> <tr> <td>Lethargy</td> <td>1</td> <td>0.1</td> <td>725</td> </tr> </tbody> </table>	Abnormal Health Events	Total Number of Events	% of Events	Total Number Vaccinations	Injection Site Paraesthesia	3	0.4	725	Vocalization at Administration	7	1.0	725	Injection site Edema	1	0.1	725	Lethargy	1	0.1	725
Abnormal Health Events	Total Number of Events	% of Events	Total Number Vaccinations																		
Injection Site Paraesthesia	3	0.4	725																		
Vocalization at Administration	7	1.0	725																		
Injection site Edema	1	0.1	725																		
Lethargy	1	0.1	725																		

Table 2: Frequency Distributions of Abnormal Health Events

Abnormal Health Event	Number of Dogs	Total Number of Vaccinations	Percent (%)
Adipsia ^d	1	725	0.14%
Anorexia ^b	2	725	0.28%
Change in blood protein	1	725	0.14%
Changes in blood phosphorous	1	725	0.14%
Circulatory shock ^c	1	725	0.14%
Convulsion ^d	1	725	0.14%
Dehydration ^b	1	725	0.14%
Diarrhea ^b	6	725	0.83%
Digestive tract disorder ^a	1	725	0.14%
Emesis ^{b, d}	6	725	0.83%
Epistaxis ^c	1	725	0.14%
External parasite	1	725	0.14%
Fracture ^c	1	725	0.14%
General pain ^c	1	725	0.14%
Hyperthermia	1	725	0.14%
Internal parasite	1	725	0.14%
Lameness ^c	1	725	0.14%
Lethargy ^{b, d}	3	725	0.41%
Muscle tremor ^d	1	725	0.14%
Polydipsia	1	725	0.14%
Pruritus	1	725	0.14%
Renal insufficiency ^b	1	725	0.14%
Skin lesion ^a	2	725	0.28%
Soft stool	1	725	0.14%
Umbilical hernia	1	725	0.14%

^a No Other Symptoms

^b Related to an episode of gastroenteritis

^c Related to an episode of trauma (hit by car)

^d Related to a witnessed but unknown ingestion while on a walk

All other dogs normal.

USDA Approval Date

April 28, 2017