



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	14P5.21
True Name	Canine Coronavirus Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	June 02, 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.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Canine coronavirus
<b>Study Purpose</b>	To demonstrate effectiveness against intestinal disease due to canine coronavirus
<b>Product Administration</b>	
<b>Study Animals</b>	
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance. Study data, however, are no longer available.
<b>USDA Approval Date</b>	December 3, 1984

<b>Study Type</b>	Safety																																																				
<b>Pertaining to</b>	All fractions																																																				
<b>Study Purpose</b>	Demonstrate safety of product under typical use conditions																																																				
<b>Product Administration</b>	Either one or two doses of vaccine 14-21 days apart by either the IM or SC route. A total of 4,079 doses were administered.																																																				
<b>Study Animals</b>	A total of 2,172 dogs of various ages and breeds																																																				
<b>Challenge Description</b>	Not applicable																																																				
<b>Interval observed after challenge</b>	No challenge. Dogs were followed for 4-7 days after each vaccination.																																																				
<b>Results</b>	<p>Frequency of adverse events: Total number of Doses Administered = 4079</p> <table border="1"> <thead> <tr> <th rowspan="2">Observation of Reaction</th> <th rowspan="2">1st Dose</th> <th rowspan="2">2nd Dose</th> <th colspan="2">No. Combined</th> </tr> <tr> <th>Number</th> <th>Percent</th> </tr> </thead> <tbody> <tr> <td>No Adverse Events</td> <td>1772</td> <td>1463</td> <td>3235</td> <td>79.3%</td> </tr> <tr> <td>Look at site</td> <td>67</td> <td>96</td> <td>163</td> <td>4.0%</td> </tr> <tr> <td>Turn in Circle</td> <td>11</td> <td>15</td> <td>26</td> <td>0.6%</td> </tr> <tr> <td>Scratch at site</td> <td>276</td> <td>240</td> <td>516</td> <td>12.7%</td> </tr> <tr> <td>Chew at site</td> <td>8</td> <td>27</td> <td>35</td> <td>0.85%</td> </tr> <tr> <td>Vocalize as in pain</td> <td>28</td> <td>12</td> <td>40</td> <td>0.99%</td> </tr> <tr> <td>Anorexia</td> <td>0</td> <td>4</td> <td>4</td> <td>0.09%</td> </tr> <tr> <td>Granuloma</td> <td>12</td> <td>32</td> <td>44</td> <td>1.1%</td> </tr> <tr> <td>Other</td> <td>0</td> <td>16</td> <td>16</td> <td>0.4%</td> </tr> </tbody> </table>	Observation of Reaction	1st Dose	2nd Dose	No. Combined		Number	Percent	No Adverse Events	1772	1463	3235	79.3%	Look at site	67	96	163	4.0%	Turn in Circle	11	15	26	0.6%	Scratch at site	276	240	516	12.7%	Chew at site	8	27	35	0.85%	Vocalize as in pain	28	12	40	0.99%	Anorexia	0	4	4	0.09%	Granuloma	12	32	44	1.1%	Other	0	16	16	0.4%
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