



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Vetmedica, Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1522.21
True Name	Equine Rhinitis A Vaccine, Killed Virus
Tradenname(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	February 04, 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	Safety																																			
Pertaining to																																				
Study Purpose	To demonstrate safety under field conditions																																			
Product Administration	Three doses, administered intramuscularly 21 days apart																																			
Study Animals	663 horses including 203 foals 1-4 months of age																																			
Challenge Description	Not applicable																																			
Interval observed after challenge	Not applicable																																			
Results	<p>Horses were observed for systemic and local injection site reactions one and three days after the first vaccination and three and seven days following the second and third vaccination.</p> <p>No injection site reactions or systemic reactions were observed in any of the 297 horses vaccinated in North Dakota. One vaccinated horse (out of 56) from the California site exhibited a slight bump (< 1 cm) at the injection site after the first vaccination that resolved within 24 hours. One vaccinated horse (out of 310) from the Missouri site exhibited generalized hives the day after the first vaccination. No treatment was administered to this horse and no further hives were observed after the second or third vaccination.</p> <p>The age distribution at the three sites of all horses treated with three doses is listed below.</p> <table border="1" data-bbox="577 1182 1428 1630"> <thead> <tr> <th rowspan="2">Horse age</th> <th colspan="3">Number of horses @ Study Site</th> </tr> <tr> <th>North Dakota</th> <th>California</th> <th>Missouri</th> </tr> </thead> <tbody> <tr> <td>1-4 months</td> <td>147</td> <td>0</td> <td>54</td> </tr> <tr> <td>5-7 months</td> <td>0</td> <td>0</td> <td>12</td> </tr> <tr> <td>8-11 months</td> <td>0</td> <td>5</td> <td>0</td> </tr> <tr> <td>1-5 years</td> <td>25</td> <td>14</td> <td>137</td> </tr> <tr> <td>6-15 years</td> <td>121</td> <td>30</td> <td>100</td> </tr> <tr> <td>>16 years</td> <td>4</td> <td>7</td> <td>7</td> </tr> <tr> <td>Total</td> <td>297</td> <td>56</td> <td>310</td> </tr> </tbody> </table>	Horse age	Number of horses @ Study Site			North Dakota	California	Missouri	1-4 months	147	0	54	5-7 months	0	0	12	8-11 months	0	5	0	1-5 years	25	14	137	6-15 years	121	30	100	>16 years	4	7	7	Total	297	56	310
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