



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Vetmedica, Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1995.22
True Name	West Nile Virus Vaccine, Killed Virus
Tradename(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.**

<b>Study Type</b>	Safety																								
<b>Pertaining to</b>	All fractions																								
<b>Study Purpose</b>	To demonstrate safety under field conditions																								
<b>Product Administration</b>	Two doses, given intramuscularly, in the rostral tail muscle for most of the alligators, 3 – 4 weeks apart																								
<b>Study Animals</b>	17,490 alligators at 7-10 months of age																								
<b>Challenge Description</b>	Not applicable																								
<b>Interval observed after challenge</b>	Not applicable																								
<b>Results</b>	<p>Alligators were monitored in a pen setting after vaccination for local or systemic injection site reactions, except for alligators in two randomly selected pens. 409 alligators were examined individually on days 1 and 3 after the first vaccination and days 3 and 7 after the second vaccination.</p> <p>No systemic reactions were observed.</p> <p>No local injection site reactions were observed following vaccination in the rostral tail muscle.</p> <p>Transient swellings at the injection site were reported within 24 hours following vaccination in the 250 alligators that were vaccinated in the right front leg. All animals reacting to vaccination in the front leg did not have reactions when re-vaccinated in the rostral tail muscle. The reactions are summarized as follows:</p> <table border="1"> <thead> <tr> <th>Location</th> <th># of Alligators</th> <th>Reactions</th> <th>Injection site</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Georgia</td> <td>409*</td> <td rowspan="2">None</td> <td rowspan="2">Rostral tail</td> </tr> <tr> <td>16,631</td> </tr> <tr> <td>Florida</td> <td>200</td> <td>None</td> <td>Rostral tail</td> </tr> <tr> <td rowspan="2">Louisiana</td> <td>250 (1<sup>st</sup> vacc)</td> <td>Local site**</td> <td>Right front leg</td> </tr> <tr> <td>250 (2<sup>nd</sup> vacc)</td> <td>None</td> <td>Rostral tail</td> </tr> <tr> <td><b>TOTAL</b></td> <td><b>17,490</b></td> <td></td> <td></td> </tr> </tbody> </table> <p>*409 alligators individually examined after each vaccination  **250 alligators had a generalized firm swelling of the forelimb that ranged from 1.5cm to 5cm difference from their unvaccinated limb and extended from the site of vaccination to the carpus. The alligators swam normally and were alert and active. Reactions resolved without treatment by study day 23, which was the day the second vaccination was given.</p>	Location	# of Alligators	Reactions	Injection site	Georgia	409*	None	Rostral tail	16,631	Florida	200	None	Rostral tail	Louisiana	250 (1 <sup>st</sup> vacc)	Local site**	Right front leg	250 (2 <sup>nd</sup> vacc)	None	Rostral tail	<b>TOTAL</b>	<b>17,490</b>		
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<b>TOTAL</b>	<b>17,490</b>																								
<b>USDA Approval Date</b>	August 30, 2011																								

<b>Study Type</b>	Safety																				
<b>Pertaining to</b>	All fractions																				
<b>Study Purpose</b>	To demonstrate safety under field conditions																				
<b>Product Administration</b>	Two doses, given intramuscularly in the rostral tail muscle, 3 - 4 weeks apart																				
<b>Study Animals</b>	180 alligators <ul style="list-style-type: none"> <li>• 80 alligators at 4 weeks of age</li> <li>• 100 alligators at 3 - 4 months of age</li> </ul>																				
<b>Challenge Description</b>	Not applicable																				
<b>Interval observed after challenge</b>	Not applicable																				
<b>Results</b>	<p>Alligators were monitored in group settings daily throughout the study. Alligators were examined individually on days 1 and 3 after the first vaccination and days 3 and 7 after the second vaccination.</p> <p>No systemic or local injection site reactions were observed in any animal in this study, as summarized the table below:</p> <table border="1"> <thead> <tr> <th>Site</th> <th>Age of Alligators</th> <th>Total # vaccinated</th> <th>Reactions after 1<sup>st</sup> vaccination</th> <th>Reactions after 2<sup>nd</sup> vaccination</th> </tr> </thead> <tbody> <tr> <td>Georgia</td> <td>4 weeks</td> <td>80</td> <td>0</td> <td>0</td> </tr> <tr> <td>Louisiana</td> <td>3 - 4 months</td> <td>100</td> <td>0</td> <td>0</td> </tr> <tr> <td colspan="2"><b>TOTAL:</b></td> <td><b>180</b></td> <td><b>0</b></td> <td><b>0</b></td> </tr> </tbody> </table>	Site	Age of Alligators	Total # vaccinated	Reactions after 1 <sup>st</sup> vaccination	Reactions after 2 <sup>nd</sup> vaccination	Georgia	4 weeks	80	0	0	Louisiana	3 - 4 months	100	0	0	<b>TOTAL:</b>		<b>180</b>	<b>0</b>	<b>0</b>
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<b>USDA Approval Date</b>	May 31, 2012																				