



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	17A2.V3
True Name	Newcastle Disease Vaccine, VG/GA Strain, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Avinew AF - No distributor specified
Date of Compilation Summary	November 16, 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>	Newcastle disease virus (NDV)
<b>Study Purpose</b>	Demonstrate efficacy against NDV
<b>Product Administration</b>	Coarse spray
<b>Study Animals</b>	Chickens at day-of-age
<b>Challenge Description</b>	Birds were challenged with GB Texas strain of Newcastle disease virus 28 days after vaccination
<b>Interval observed after challenge</b>	Birds were observed daily for 14 days after challenge for clinical signs of disease.
<b>Results</b>	<p>Vaccinates and controls were evaluated for Newcastle disease clinical signs per the criteria in 9 CFR 113.329(c)(4).</p> <p>Birds with clinical signs or mortality due to NDV:  Group 4 (Vaccinates): 0/30  Group 5 (Controls): 29/29</p> <p>Requirements of 9 CFR 113.329(c)(4) were met.</p> <p>Raw data on attached page.</p>
<b>USDA Approval Date</b>	November 21, 2013

**Table 1: List of affected birds.**

Group	Bird ID	Death	Outcome for Newcastle Disease Virus
5 Controls	794	+	Positive
	836	+	Positive
	793	+	Positive
	792	+	Positive
	832	+	Positive
	835	+	Positive
	791	+	Positive
	840	+	Positive
	800	+	Positive
	834	+	Positive
	839	+	Positive
	799	+	Positive
	729	+	Positive
	728	+	Positive
	798	+	Positive
	727	+	Positive
	726	+	Positive
	838	+	Positive
	797	+	Positive
	725	+	Positive
	724	+	Positive
	796	+	Positive
	723	+	Positive
	722	+	Positive
	831	+	Positive
	833	+	Positive
	837	+	Positive
	795	+	Positive
721	+	Positive	

+ = Birds were found dead. All deaths were attributable to Newcastle Disease Virus.

<b>Study Type</b>	Safety																																																											
<b>Pertaining to</b>	ALL																																																											
<b>Study Purpose</b>	Demonstrate safety under field conditions																																																											
<b>Product Administration</b>	1 dose by coarse spray																																																											
<b>Study Animals</b>	Chickens at day-of-age																																																											
<b>Challenge Description</b>	Not applicable																																																											
<b>Interval observed after challenge</b>	Mortality was recorded daily for 21 days after vaccination. Air sacculitis condemnation rates were collected.																																																											
<b>Results</b>	<table border="1"> <thead> <tr> <th>Location</th> <th>Treatment</th> <th>Total Placed</th> <th>21 Day Mortality</th> <th>% Mortality</th> <th>% Condemnations</th> </tr> </thead> <tbody> <tr> <td>1*</td> <td>Spray</td> <td>75,061</td> <td>2300</td> <td>3.1</td> <td>0.00</td> </tr> <tr> <td>1*</td> <td>Control</td> <td>75,119</td> <td>917</td> <td>1.2</td> <td>0.01</td> </tr> <tr> <td>2</td> <td>Spray</td> <td>36,400</td> <td>703</td> <td>1.9</td> <td>0.02</td> </tr> <tr> <td>2</td> <td>Control</td> <td>36,400</td> <td>691</td> <td>1.9</td> <td>0.09</td> </tr> <tr> <td>3</td> <td>Spray</td> <td>65,000</td> <td>1178</td> <td>1.8</td> <td>0.00</td> </tr> <tr> <td>3</td> <td>Control</td> <td>59,000</td> <td>1407</td> <td>2.4</td> <td>0.00</td> </tr> <tr> <td>4*</td> <td>Spray</td> <td>45,100</td> <td>2957</td> <td>6.6</td> <td>0.17</td> </tr> <tr> <td>4*</td> <td>Control</td> <td>45,100</td> <td>2223</td> <td>4.9</td> <td>0.19</td> </tr> </tbody> </table>						Location	Treatment	Total Placed	21 Day Mortality	% Mortality	% Condemnations	1*	Spray	75,061	2300	3.1	0.00	1*	Control	75,119	917	1.2	0.01	2	Spray	36,400	703	1.9	0.02	2	Control	36,400	691	1.9	0.09	3	Spray	65,000	1178	1.8	0.00	3	Control	59,000	1407	2.4	0.00	4*	Spray	45,100	2957	6.6	0.17	4*	Control	45,100	2223	4.9	0.19
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<p>*For both sites with higher mortality in the test (spray) than control houses, birds from different hen flocks were used for the test and control houses. Information from the cooperators strongly suggested a connection between the reported mortality and the hen flocks that provided chicks for the test houses.</p> <p>No adverse reactions were observed.</p>																																																												
<b>USDA Approval Date</b>	July 18, 2016																																																											