# Summary of Studies Supporting USDA Product Licensure

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|---|---|
| Establishment Name | Boehringer Ingelheim Animal Health USA Inc. |
| USDA Vet Biologics Establishment Number | 124 |
| Product Code | 17H1.R1 |
| True Name | Marek's Disease-Newcastle Disease Vaccine, Serotypes 2 & 3, Live Virus, Live Marek's Disease Vector |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | NEWXXITEK HVT+ND & SB1 - No distributor specified |
| Date of Compilation Summary | May 17, 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** | Efficacy |
| **Pertaining to** | Marek's disease virus |
| **Study Purpose** | Demonstrate efficacy against very virulent Marek's Disease virus |
| **Product Administration** | 1 dose by in ovo route |
| **Study Animals** | 18- to 19-day-old embryos were divided into 4 groups<br><br>Group 1 vaccinated with test product and challenged<br>Group 2 sham vaccinated and challenged (control)<br>Group 3 sham vaccinated non-challenged (control)<br>Group 4 vaccinated with HVT vaccine and challenged |
| **Challenge Description** | Serotype 1, RB1B very virulent Marek's disease virus |
| **Interval observed after challenge** | Birds observed daily for clinical signs for 45 days post challenge |
| **Results** | Vaccinates and controls were evaluated in terms of Marek's disease clinical signs and/or grossly observable lesions per the criteria in 9 CFR 113.330(c).<br><br>Birds with clinical signs and/or observable lesions:<br>Group 1: 5/28<br>Group 2: 34/34<br>Group 3: 0/25<br>Group 4: 18/34<br><br>Requirements of 9 CFR 113.330(c) were met.<br><br>Raw data on attached page |
| **USDA Approval Date** | March 25, 2014 |

| Group/Bird | Paralysis | Locomotive | Emaciation | De-pression | Liver | Spleen | Heart | Muscle | Gonads | Kidneys | Other Gross Lesions | Comments |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1/1 | | | X | | | | | | X | | | |
| 1/2 | | | | | | | | | X | X | | |
| 1/3 | | X | X | | | | | | X | X | | |
| 1/4 | | | | | | | | | X | | | |
| 1/5 | | | | | | | | | X | X | | |
| 2/1 | | | | X | | X | | | X | | | |
| 2/2 | | | | X | X | X | X | | | X | | |
| 2/3 | | X | | | | | | | X | X | | |
| 2/4 | | | | X | X | | X | | | | | |
| 2/5 | | | | X | X | X | | | | X | | |
| 2/6 | | | | | | | | | | X | | |
| 2/7 | | | | X | X | X | X | | | | | |
| 2/8 | | | X | | | X | | | | X | | |
| 2/9 | | | | X | | | | | X | X | | |
| 2/10 | | | X | | | X | X | | X | X | | |
| 2/11 | | | | X | X | | | | X | X | | |
| 2/12 | | | | X | X | X | X | | | X | | |
| 2/13 | | X | | X | X | X | | | | | | |
| 2/14 | | | | X | X | X | X | | | | | |
| 2/15 | | | | | | | | | | X | | |
| 2/16 | | | X | X | | | | X | X | X | | |
| 2/17 | | | | X | | X | | | | X | | |
| 2/18 | | | | X | X | | X | | X | X | | |
| 2/19 | | | X | X | | X | | | X | X | | |
| 2/20 | | | | X | | | | X | X | | | |
| 2/21 | | | | | X | X | | | | X | | |
| 2/22 | | | X | X | | X | | | X | X | | |
| 2/23 | | | | X | | X | | | | X | | |
| 2/24 | | | | X | | | X | | X | X | | |
| 2/25 | | | | X | | X | | | X | X | | |
| 2/26 | | | | X | | | | | | | | |
| 2/27 | | | | X | | | | | | X | | |
| 2/28 | | X | | X | | | | | | X | | |
| 2/29 | | | | X | | X | X | | | X | | |
| 2/30 | | | | X | | X | X | | | X | X | Intestinal tract |
| 2/31 | | X | X | | | | | X | X | X | | |
| 2/32 | | | | X | X | X | | | | X | | |
| 2/33 | | | | X | | X | | | | X | | |
| 2/34 | | | | X | X | X | | | | X | | |
| 4/1 | | | | | X | X | X | | X | X | | |

| Group/Bird | Paralysis | Locomotive | Emaciation | De-pression | Liver | Spleen | Heart | Muscle | Gonads | Kidneys | Other Gross Lesions | Comments |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 4/2 | | | | | | | | X | X | X | X | Intestinal tract (other) |
| 4/3 | | | | | | | | | X | | | |
| 4/4 | X | | | | | | | | X | | | |
| 4/5 | | | X | X | | | X | | | X | X | Intestinal tract |
| 4/6 | | | | X | | X | | X | X | | X | Intestinal tract |
| 4/7 | | | | | | | | | | | X | Intestinal tract |
| 4/8 | | | | | | | | | X | | X | Intestinal tract |
| 4/9 | | | X | X | | X | | | X | X | | |
| 4/10 | | | | | | | | | | X | | |
| 4/11 | | X | | | | | | | X | | | |
| 4/12 | | | X | | | | | | | | X | Intestinal tract |
| 4/13 | | X | | X | | | X | | X | | | |
| 4/14 | | X | | X | | | X | X | | X | | |
| 4/15 | | X | | X | | | X | X | | X | | |
| 4/16 | | X | | | | | | | X | X | | |
| 4/17 | | | | | | | X | | | X | | |
| 4/18 | | | | | X | X | X | | | X | | |

No clinical signs or lesions were observed in remaining birds in study.

| | |
|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | Marek's disease virus |
| **Study Purpose** | Demonstrate efficacy against very virulent Marek's Disease virus |
| **Product Administration** | 1 dose by Subcutaneous route |
| **Study Animals** | Day-old chicks divided into 4 groups<br><br>Group 1 vaccinated with test product and challenged<br>Group 2 sham vaccinated and challenged (control)<br>Group 3 sham vaccinated non-challenged (control)<br>Group 4 vaccinated with HVT vaccine and challenged |
| **Challenge Description** | Serotype 1, RB1B very virulent Marek's disease virus |
| **Interval observed after challenge** | Birds observed daily for clinical signs for 45 days post challenge |
| **Results** | Vaccinates and controls were evaluated in terms of Marek's disease clinical signs and/or grossly observable lesions per the criteria in 9 CFR 113.330(c).<br><br>Birds with clinical signs and/or observable lesions:<br>Group 1: 5/35<br>Group 2: 35/35<br>Group 3: 0/25<br>Group 4: 9/34<br><br>Requirements of 9 CFR 113.330(c) were met.<br><br>Raw data on attached page |
| **USDA Approval Date** | April 3, 2014 |

| Group/ Bird | Paralysis | Locomotive | Emaciation | Depression | Other Clinical Signs | Liver | Spleen | Heart | Muscle | Gonads | Kidneys | Other Gross Lesions | Comments |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1/1 | | | | | | | | | | | | X | Intestinal tract |
| 1/2 | | | | | | X | X | X | | X | X | | |
| 1/3 | | | | | | | | X | | X | | | |
| 1/4 | | | | | | | | | | X | | | |
| 1/5 | | X | | X | | X | | | | X | X | | |
| 2/1 | | | | X | | | X | | | | X | | |
| 2/2 | | X | | X | | X | | X | | | X | | |
| 2/3 | | | | X | | | X | | | X | | | |
| 2/4 | | | | X | | | X | | | | | | |
| 2/5 | | X | | X | | | | | | X | | | |
| 2/6 | | | | X | | | X | X | | | | | |
| 2/7 | | | | X | | X | X | X | | | | | |
| 2/8 | | | | | | | | | | | X | | |
| 2/9 | | | | X | X | | | | | | | | Torticollis |
| 2/10 | | | | | | | X | | | | X | | |
| 2/11 | | | X | X | | | | | | | X | | |
| 2/12 | | | | X | | | | | | X | X | | |
| 2/13 | | | | X | | | | | | | | | |
| 2/14 | | | | X | | | X | | | | X | | |
| 2/15 | | | | X | | | | | | | | | |
| 2/16 | | X | | X | | | X | X | | | | | |
| 2/17 | | | | X | | | X | | | | | | |
| 2/18 | | | X | X | | | X | X | X | | X | | |
| 2/19 | | X | | X | | | | | | | | | |
| 2/20 | | | | X | | X | X | | | | X | | |
| 2/21 | | | | X | | X | X | | | | X | | |
| 2/22 | | | | | | | | X | | X | | X | Intestinal tract |
| 2/23 | | | | X | | | X | | X | | X | | |
| 2/24 | | X | | | | X | X | X | | X | X | | |
| 2/25 | | | | X | | | | | | | X | | |
| 2/26 | | | | X | | | | | | | | | Large retained yolk |
| 2/27 | | | | X | | | X | | | | X | | |
| 2/28 | X | | | | | | | | | | | | |
| 2/29 | | | | X | | | X | | | | X | | |
| 2/30 | | | | X | | | | X | X | X | X | | |
| 2/31 | | | | X | | | X | | | | X | | |
| 2/32 | | | | X | | | | X | | | X | | |
| 2/33 | | | | X | | X | X | | X | | | | |
| 2/34 | | | | X | | | X | | | X | | | |
| 2/35 | | | | X | X | | | | | | | | Torticollis |
| 4/1 | | | | | | | | | | | | X | Intestinal tract |
| 4/2 | | X | | | | | | | | | | | |

| Group/ Bird | Paralysis | Locomotive | Emaciation | Depression | Other Clinical Signs | Liver | Spleen | Heart | Muscle | Gonads | Kidneys | Other Gross Lesions | Comments |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 4/3 | | | | | | | | | | X | | | |
| 4/4 | | | | | | | | | | | X | | |
| 4/5 | | | | | | | X | X | | X | X | | |
| 4/6 | | | | X | | | | | X | X | X | | |
| 4/7 | | X | X | X | | | | X | X | | X | | |
| 4/8 | | | | | | | | | | X | X | | |
| 4/9 | | X | | X | | X | | | X | X | X | | |

No clinical signs or lesions were observed in remaining birds in the study.

| | |
|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | Newcastle disease virus (NDV) |
| **Study Purpose** | Demonstrate efficacy against virulent Newcastle disease |
| **Product Administration** | 1 dose by subcutaneous route |
| **Study Animals** | Day old chicks were divided into 2 groups<br><br>Group 1 vaccinated and challenged<br>Group 2 sham vaccinated and challenged (control) |
| **Challenge Description** | NDV Texas GB |
| **Interval observed after challenge** | Birds observed daily for clinical signs for 14 days post challenge |
| **Results** | Vaccinates and controls were evaluated in terms of Newcastle disease clinical signs per the criteria in 9 CFR 113.329(c)(4).<br><br>Birds with clinical signs:<br>Group 1: 0/30<br>Group 2: 30/30<br><br>Requirements of 9 CFR 113.329(c)(4) were met.<br><br>Raw data on attached page |
| **USDA Approval Date** | March 10, 2014 |

| Group/Bird | NDV Result based on clinical signs |
|---|---|
| 2/1 | Positive |
| 2/2 | Positive |
| 2/3 | Positive |
| 2/4 | Positive |
| 2/5 | Positive |
| 2/6 | Positive |
| 2/7 | Positive |
| 2/8 | Positive |
| 2/9 | Positive |
| 2/10 | Positive |
| 2/11 | Positive |
| 2/12 | Positive |
| 2/13 | Positive |
| 2/14 | Positive |
| 2/15 | Positive |
| 2/16 | Positive |
| 2/17 | Positive |
| 2/18 | Positive |
| 2/19 | Positive |
| 2/20 | Positive |
| 2/21 | Positive |
| 2/22 | Positive |
| 2/23 | Positive |
| 2/24 | Positive |
| 2/25 | Positive |
| 2/26 | Positive |
| 2/27 | Positive |
| 2/28 | Positive |
| 2/29 | Positive |
| 2/30 | Positive |

| | |
|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | Newcastle disease virus (NDV) |
| **Study Purpose** | Demonstrate efficacy against virulent Newcastle disease |
| **Product Administration** | 1 dose by *in ovo* route |
| **Study Animals** | 18 to 19 day old embryos were divided into 2 groups<br><br>Group 3 vaccinated and challenged<br>Group 4 sham vaccinated and challenged (control) |
| **Challenge Description** | NDV Texas GB |
| **Interval observed after challenge** | Birds observed daily for clinical signs for 14 days post challenge |
| **Results** | Vaccinates and controls were evaluated in terms of Newcastle disease clinical signs per the criteria in 9 CFR 113.329(c)(4).<br><br>Birds with clinical signs:<br>Group 3: 2/39<br>Group 4: 40/40<br><br>Requirements of 9 CFR 113.329(c)(4) were met.<br><br>Raw data on attached page |
| **USDA Approval Date** | March 27, 2014 |

| Group/Bird | Paralysis | Muscular Tremors | NDV Result |
|---|---|---|---|
| 3/1 | | X | Positive |
| 3/2 | | | Positive |
| 4/1 | | | Positive |
| 4/2 | | X | Positive |
| 4/3 | | | Positive |
| 4/4 | | | Positive |
| 4/5 | | X | Positive |
| 4/6 | | X | Positive |
| 4/7 | | X | Positive |
| 4/8 | | | Positive |
| 4/9 | | | Positive |
| 4/10 | | | Positive |
| 4/11 | | X | Positive |
| 4/12 | | | Positive |
| 4/13 | | X | Positive |
| 4/14 | | | Positive |
| 4/15 | | X | Positive |
| 4/16 | | X | Positive |
| 4/17 | | X | Positive |
| 4/18 | | | Positive |
| 4/19 | | X | Positive |
| 4/20 | | | Positive |
| 4/21 | | X | Positive |
| 4/22 | | X | Positive |
| 4/23 | | | Positive |
| 4/24 | | X | Positive |
| 4/25 | | X | Positive |
| 4/26 | | | Positive |
| 4/27 | | X | Positive |
| 4/28 | | | Positive |
| 4/29 | | | Positive |
| 4/30 | | | Positive |
| 4/31 | | | Positive |
| 4/32 | | | Positive |
| 4/33 | | | Positive |
| 4/34 | | X | Positive |
| 4/35 | | | Positive |
| 4/36 | | X | Positive |
| 4/37 | | | Positive |
| 4/38 | | | Positive |
| 4/39 | | | Positive |
| 4/40 | | | Positive |

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>All</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate safety of product under typical use conditions</td></tr>
<tr><td>Product Administration</td><td>1 dose by either the in ovo or subcutaneous route</td></tr>
<tr><td>Study Animals</td><td>Poultry, 18 to 19 day-old embryos or day-old chicks.<br>75,600 were vaccinated by in ovo route, 48,029 were vaccinated by subcutaneous route and 181,400 were kept as controls treated by the typical site vaccination program. Animals were observed daily for mortality through 21 days after vaccination.</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>Not applicable</td></tr>
<tr><td>Results</td><td>No adverse reactions attributable to the vaccine were noted.
<table>
<tr><th>Location</th><th>Treatment</th><th>Total Placed</th><th>21 Day Mortality</th><th>% Mortality</th><th>% Hatchability</th></tr>
<tr><td>1</td><td>In ovo</td><td>22,600</td><td>794</td><td>3.5</td><td>74.7</td></tr>
<tr><td rowspan="2">1</td><td>Control</td><td rowspan="2">24,700</td><td rowspan="2">721</td><td rowspan="2">2.9</td><td rowspan="6">87.4</td></tr>
<tr><td>In ovo</td></tr>
<tr><td rowspan="2">1</td><td>Control</td><td rowspan="2">24,700</td><td rowspan="2">815</td><td rowspan="2">3.3</td></tr>
<tr><td>In ovo</td></tr>
<tr><td rowspan="2">1</td><td>Control</td><td rowspan="2">24,700</td><td rowspan="2">679</td><td rowspan="2">2.7</td></tr>
<tr><td>In ovo</td></tr>
<tr><td>2</td><td>In ovo</td><td>20,200</td><td>398</td><td>2</td><td rowspan="2">89.3</td></tr>
<tr><td>2</td><td>In ovo</td><td>20,300</td><td>369</td><td>1.8</td></tr>
<tr><td rowspan="2">2</td><td>Control</td><td rowspan="2">19,100</td><td rowspan="2">410</td><td rowspan="2">2.1</td><td rowspan="2">86.6</td></tr>
<tr><td>In ovo</td></tr>
<tr><td rowspan="2">2</td><td>Control</td><td rowspan="2">19,100</td><td rowspan="2">678</td><td rowspan="2">3.5</td><td rowspan="2">N/A</td></tr>
<tr><td>SQ</td></tr>
<tr><td rowspan="2">2</td><td>Control</td><td rowspan="2">19,100</td><td rowspan="2">791</td><td rowspan="2">4.1</td><td rowspan="2">N/A</td></tr>
<tr><td>SQ</td></tr>
<tr><td>3</td><td>SQ</td><td>24,000</td><td>542</td><td>2.3</td><td>N/A</td></tr>
<tr><td>3</td><td>SQ</td><td>24,029</td><td>267</td><td>1.1</td><td>N/A</td></tr>
<tr><td rowspan="2">3</td><td>Control</td><td rowspan="2">25,000</td><td rowspan="2">332</td><td rowspan="2">1.3</td><td rowspan="2">N/A</td></tr>
<tr><td>SQ</td></tr>
<tr><td rowspan="2">3</td><td>Control</td><td rowspan="2">25,000</td><td rowspan="2">325</td><td rowspan="2">1.3</td><td rowspan="2">N/A</td></tr>
<tr><td>SQ</td></tr>
</table>
N/A is not applicable</td></tr>
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|---|---|
| **USDA Approval Date** | October 19, 2017 |

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>All</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate safety of product under typical use conditions</td></tr>
<tr><td>Product Administration</td><td>1 dose by either the in ovo or subcutaneous route</td></tr>
<tr><td>Study Animals</td><td>Poultry, 18 to 19 day-old embryos or day-old chicks.<br>75,600 were vaccinated by in ovo route, 48,029 were vaccinated by subcutaneous route and 181,400 were kept as controls treated by the typical site vaccination program. Animals were observed daily for mortality through 21 days after vaccination.</td></tr>
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<tr><td>3</td><td>Control<br>SQ</td><td>25,000</td><td>325</td><td>1.3</td><td>N/A</td></tr>
</table>
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<tr><td>USDA Approval Date</td><td>October 19, 2017</td></tr>
</table>