Summary of Studies Supporting USDA Product Licensure

Establishment Name	Ceva Animal Health, LLC
USDA Vet Biologics Establishment Number	368
Product Code	16L1.00
True Name	Marek's Disease Vaccine, Serotype 1, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Biomune Company CEVAC MD RISPENS - Biomune Company CEVAC MD RISPENS - CEVA Saude Animal Ltda. (Brazil) CEVAC MD RISPENS - No distributor specified
Date of Compilation Summary	February 10, 2021

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 (MDV)
Study Purpose	To demonstrate efficacy against MDV
Product Administration	*In ovo* and subcutaneous route
Study Animals	Chickens
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	March 14, 2002

Study Type	Efficacy
Pertaining to	Marek's Disease Virus (MDV)
Study Purpose	To demonstrate efficacy against MDV
Product Administration	*In ovo* route and Subcutaneous route
Study Animals	Chickens
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	March 14, 2002

<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>To demonstrate safety under field conditions</td></tr>
<tr><td>Product Administration</td><td>1. One dose administered via the in ovo route
2. One dose administered via the subcutaneous (SQ) route</td></tr>
<tr><td>Study Animals</td><td>1. Commercial chicken embryos at 18 to 19 days of incubation at three independent sites (in ovo)
2. Commercial chickens at day of age at three independent sites (SQ)</td></tr>
<tr><td>Challenge Description</td><td>Not Applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed daily for mortality through 21 days of age (in ovo vaccination) and 21 days post vaccination (SQ vaccination).</td></tr>
<tr><td>Results</td><td>Chickens were observed through 21 days of age
<table>
<tr><th>Location</th><th>Treatment Group</th><th>% Hatchability</th><th>Total Chicks Placed</th><th>% Mortality</th><th>Observations</th></tr>
<tr><td rowspan="2">1</td><td>In ovo Vaccinate</td><td>87.8</td><td>21,249</td><td>0.90</td><td>No adverse reactions</td></tr>
<tr><td>Control</td><td>87.7</td><td>17,071</td><td>0.98</td><td>No adverse reactions</td></tr>
<tr><td rowspan="2">2</td><td>In ovo Vaccinate</td><td>89.6</td><td>2,000</td><td>1.80</td><td>No adverse reactions</td></tr>
<tr><td>Control</td><td>88.5</td><td>2,000</td><td>1.95</td><td>No adverse reactions</td></tr>
<tr><td rowspan="2">3</td><td>In ovo Vaccinate</td><td>83.8</td><td>913</td><td>7.00</td><td>No adverse reactions</td></tr>
<tr><td>Control</td><td>83.2</td><td>1,132</td><td>9.45</td><td>No adverse reactions</td></tr>
<tr><td rowspan="2">4</td><td>SQ Vaccinate</td><td>Not Applicable</td><td>13,500</td><td>1.50</td><td>No adverse reactions</td></tr>
<tr><td>Control</td><td>Not Applicable</td><td>13,500</td><td>1.13</td><td>No adverse reactions</td></tr>
<tr><td rowspan="2">5</td><td>SQ Vaccinate</td><td>Not Applicable</td><td>9,000</td><td>1.07</td><td>No adverse reactions</td></tr>
<tr><td>Control</td><td>Not Applicable</td><td>13,000</td><td>1.61</td><td>No adverse reactions</td></tr>
<tr><td rowspan="2">6</td><td>SQ Vaccinate</td><td>Not Applicable</td><td>1,500</td><td>0.53</td><td>No adverse reactions</td></tr>
<tr><td>Control</td><td>Not Applicable</td><td>500</td><td>0.20</td><td>No adverse reactions</td></tr>
</table></td></tr>
<tr><td>USDA Approval Date</td><td>January 12, 2010</td></tr>
</table>