



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Ceva Animal Health, LLC
USDA Vet Biologics Establishment Number	368
Product Code	1281.R1
True Name	Bursal Disease-Marek's Disease Vaccine, Serotypes 1 & 3, Live Virus, Live Marek's Disease Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Biomune Company VECTORMUNE HVT IBD & RISPENS - Ceva Saude Animal LTDA VECTORMUNE HVT IBD & RISPENS - No distributor specified
Date of Compilation Summary	February 05, 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	Infectious Bursal Disease Virus
Study Purpose	To demonstrate efficacy against IBDV Delaware Variant E and IBDV Standard strains
Product Administration	<i>In ovo</i>
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	May 20, 2003

Study Type	Efficacy
Pertaining to	Infectious Bursal Disease Virus (IBDV) Standard and Variant types
Study Purpose	To demonstrate efficacy against IBDV Standard and Variant types
Product Administration	Subcutaneous
Study Animals	
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	January 31, 2002

Study Type	Efficacy
Pertaining to	Marek's Disease Virus (MDV)
Study Purpose	To demonstrate efficacy against MDV
Product Administration	<i>In ovo</i> and subcutaneous
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 16, 2007

Study Type	Efficacy
Pertaining to	Marek's Disease Virus (MDV)
Study Purpose	To demonstrate efficacy against Marek's Disease Virus (MDV) RB1/B
Product Administration	Chickens were vaccinated at day of age via the subcutaneous (SQ) 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 16, 2007

Study Type	Safety																																												
Pertaining to	All																																												
Study Purpose	To demonstrate safety under typical field conditions																																												
Product Administration	One dose administered via the <i>in ovo</i> route																																												
Study Animals	Commercial chicken embryos at 18 to 19 days of incubation at three independent sites																																												
Challenge Description	Not applicable																																												
Interval observed after challenge	Not applicable																																												
Results	Chickens were observed for 21 days after placement at day-of-age																																												
	<table border="1"> <thead> <tr> <th>Location</th> <th>Treatment</th> <th>% Hatchability</th> <th>Total Chicks Placed</th> <th># Deaths</th> <th>% Mortality</th> </tr> </thead> <tbody> <tr> <td rowspan="2">1</td> <td>Vaccinate</td> <td>87.92</td> <td>20,890</td> <td>640</td> <td>3.06</td> </tr> <tr> <td>Control</td> <td>89.35</td> <td>19,300</td> <td>450</td> <td>2.33</td> </tr> <tr> <td rowspan="2">2</td> <td>Vaccinate</td> <td>87.74</td> <td>21,321</td> <td>216</td> <td>1.01</td> </tr> <tr> <td>Control</td> <td>87.67</td> <td>17,071</td> <td>168</td> <td>0.98</td> </tr> <tr> <td rowspan="2">3</td> <td>Vaccinate</td> <td>89.75</td> <td>24,700</td> <td>721</td> <td>2.92</td> </tr> <tr> <td>Control</td> <td>75.12</td> <td>24,100</td> <td>583</td> <td>2.42</td> </tr> </tbody> </table>						Location	Treatment	% Hatchability	Total Chicks Placed	# Deaths	% Mortality	1	Vaccinate	87.92	20,890	640	3.06	Control	89.35	19,300	450	2.33	2	Vaccinate	87.74	21,321	216	1.01	Control	87.67	17,071	168	0.98	3	Vaccinate	89.75	24,700	721	2.92	Control	75.12	24,100	583	2.42
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USDA Approval Date	October 19, 2009																																												

Study Type	Safety																																					
Pertaining to	All																																					
Study Purpose	To demonstrate safety under typical field conditions																																					
Product Administration	Subcutaneous																																					
Study Animals	Commercial chickens at day of age at three independent sites																																					
Challenge Description	Not Applicable																																					
Interval observed after challenge	No challenge. Commercial chickens were observed daily through 21 days of age.																																					
Results	<table border="1"> <thead> <tr> <th rowspan="2">Location</th> <th rowspan="2">Treatment Group</th> <th rowspan="2">Number of Chickens</th> <th colspan="2">Mortality</th> </tr> <tr> <th>No. of Deaths</th> <th>%</th> </tr> </thead> <tbody> <tr> <td rowspan="2">1</td> <td>Vaccinate</td> <td>30,700</td> <td>444</td> <td>1.45</td> </tr> <tr> <td>Control</td> <td>14,600</td> <td>261</td> <td>1.79</td> </tr> <tr> <td rowspan="2">2</td> <td>Vaccinate</td> <td>13,000</td> <td>282</td> <td>2.17</td> </tr> <tr> <td>Control</td> <td>13,000</td> <td>318</td> <td>2.45</td> </tr> <tr> <td rowspan="2">3</td> <td>Vaccinate</td> <td>20,907</td> <td>1,006</td> <td>4.81</td> </tr> <tr> <td>Control</td> <td>20,778</td> <td>960</td> <td>4.62</td> </tr> </tbody> </table> <p>No adverse reactions were observed in any treatment group following vaccination or throughout the observation period.</p>				Location	Treatment Group	Number of Chickens	Mortality		No. of Deaths	%	1	Vaccinate	30,700	444	1.45	Control	14,600	261	1.79	2	Vaccinate	13,000	282	2.17	Control	13,000	318	2.45	3	Vaccinate	20,907	1,006	4.81	Control	20,778	960	4.62
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