Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	16G1.R0
True Name	Marek's Disease Vaccine, Serotypes 1 & 3, Live Virus, Live Herpesvirus Chimera
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
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, serotype 1
Study Purpose	Demonstrate efficacy against very virulent Marek's disease
Product Administration	One dose administered *in ovo*
Study Animals	SPF eggs divided into 4 groups Group 1 vaccinated with test product and challenged Group 2 sham vaccinated and challenged (control) Group 3 sham vaccinated and not challenged (control) Group 4 vaccinated with a serotype 3 Marek's vaccine and challenged (control)
Challenge Description	Serotype-1 (SR-1) RB1B strain administered at 5 days of age
Interval observed after challenge	Observed daily for 50 days and then evaluated for internal lesions
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)(4) & (5). Birds with clinical signs and/or observable lesions: Group 1: 7/35 Group 2: 34/34 Group 3: 0/35 Group 4: 9/35 Requirements of 9 CFR 113.330(c)(4) & (5) were met. Raw data on attached page
USDA Approval Date	November 28, 2016

Raw data shown below for birds classified as positive. All other birds normal.

Group/Bird	Paralysis	Locomotive_Signs	Emaciation	Depression	Other Clinical Signs	Liver	Spleen	Heart	Muscle	Gonads	Kidneys	Other Gross Lesions	Comments
1/1							X			X	X		
1/2		X		X		X	X				X		
1/3		X		X		X	X			X	X		
1/4		X		X		X	X			X	X		
1/5										X	X		
1/6	X		X	X		X	X						
1/7			X										Distended crop
2/1				X									
2/2				X			X				X		
2/3				X			X			X			
2/4				X							X		
2/5				X						X	X		
2/6				X			X						
2/7				X			X						
2/8				X			X			X	X		
2/9				X			X			X			
2/10				X			X						
2/11				X									
2/12				X		X	X				X		
2/13				X			X						
2/14				X			X				X		
2/15				X							X		
2/16							X		X				
2/17				X						X	X		
2/18				X			X			X	X		
2/19				X			X						
2/20				X			X			X			

Group/Bird	Paralysis	Locomotive_Signs	Emaciation	Depression	Other Clinical Signs	Liver	Spleen	Heart	Muscle	Gonads	Kidneys	Other Gross Lesions	Comments
2/21				X				X					
2/22				X			X			X			
2/23				X			X						
2/24				X		X				X			
2/25				X		X	X						
2/26				X		X	X						
2/27				X			X			X			
2/28				X			X				X		
2/29				X						X	X		
2/30				X			X			X			
2/31				X			X						
2/32				X						X			
2/33	X						X			X	X		
2/34				X			X				X		
4/1	X										X		
4/2									X	X	X		
4/3						X	X			X	X		
4/4				X						X	X		
4/5	X			X						X	X		
4/6		X		X		X	X				X		
4/7		X		X							X		
4/8							X	X	X	X	X		
4/9	X												

Study Type	Efficacy
Pertaining to	Marek's Disease serotype 1
Study Purpose	Demonstrate efficacy against very virulent Marek's disease
Product Administration	One dose administered by subcutaneous route
Study Animals	SPF birds divided into 4 groups Group 2 vaccinated with test product and challenged Group 3 sham vaccinated and challenged (control) Group 4 sham vaccinated non-challenged (control) Group 5 vaccinated with a serotype 3 Marek's vaccine and challenged (control)
Challenge Description	Serotype-1 (SR-1) RB1B strain administered at 4 days of age
Interval observed after challenge	Observed daily for 50 days and then evaluated for internal lesions
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)(4) & (5). Birds with clinical signs and/or observable lesions: Group 2: 6/35 Group 3: 33/35 Group 4: 0/35 Group 5: 10/35 Requirements of 9 CFR 113.330(c)(4) & (5) were met. Raw data on attached page
USDA Approval Date	July 16, 2013

Raw data shown below for birds classified as positive. All other birds normal.

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

Group/Bird	Paralysis	Locomotive	Emaciation	Depression	Other Clinical Signs	Liver	Spleen	Heart	Muscle	Gonads	Kidneys	Other Gross Lesions
5/1					X	X					X	
5/2									X	X		
5/3										X		
5/4									X	X		
5/5								X	X	X		
5/6							X		X	X	X	
5/7									X		X	
5/8										X		
5/9									X			
5/10									X	X		

<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>Commercial chicken eggs at 18 to 19 days of embryonation or chickens at one day of age. At each of the three sites, one group received the test vaccine and one group received vaccinations according to site standard practices. Hatchability for in ovo vaccinated groups was recorded. Animals were observed daily for mortality for 21 days.</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>
<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 rowspan="2">1</td><td rowspan="2">In ovo</td><td>15,500</td><td>330</td><td>2.1</td><td rowspan="2">81.7</td></tr>
<tr><td>15,500</td><td>310</td><td>2.0</td></tr>
<tr><td>1</td><td>Control</td><td>15,500</td><td>251</td><td>1.6</td><td>86.5</td></tr>
<tr><td>2</td><td>In ovo</td><td>20,000</td><td>333</td><td>1.7</td><td>90.1</td></tr>
<tr><td>2</td><td>Control</td><td>20,000</td><td>277</td><td>1.4</td><td>91.8</td></tr>
<tr><td>3</td><td>SQ</td><td>22,500</td><td>388</td><td>1.7</td><td>N/A</td></tr>
<tr><td>3</td><td>Control</td><td>22,540</td><td>756</td><td>3.4</td><td>N/A</td></tr>
</table>
N/A = not applicable

No adverse reactions attributable to the vaccine were recorded.
</td></tr>
<tr><td>USDA Approval Date</td><td>July 2, 2018</td></tr>
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