Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	16L1.R0
True Name	Marek's Disease Vaccine, Serotype 1, Live Herpesvirus Chimera
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Prevexxion RN - 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	vvMDV serotype 1
Study Purpose	Demonstrate efficacy against very virulent Marek's disease
Product Administration	One dose administered subcutaneously
Study Animals	Day-old chicks divided into 4 groups Group 1 vaccinated with Code 16L1.R0 and challenged Group 2 sham vaccinated and challenged (control) Group 3 sham vaccinated non-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 4 days post vaccination
Interval observed after challenge	Observed daily for 7 weeks 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: 5/34 Group 2: 31/34 Group 3: 0/35 Group 4: 8/33 Requirements of 9 CFR 113.330(c)(4) & (5) were met. Raw data on attached page
USDA Approval Date	December 20, 2011

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

			Tumors In									
Group/Bird	**Emaciation**	**Locomotor/ Paralysis**	**Kidney**	**Spleen**	**Gonads**	**Breast**	**Liver**	**Intestine**	**Heart**	**Ascites**	**Yolk Sac Infection**	**Reason Not Given**
Group 1/1		x										
Group 1/2	x											
Group 1/3												x
Group 1/4	x			x								
Group 1/5			x									
Group 2/1	x											
Group 2/2		x			x							
Group 2/3		x			x							
Group 2/4	x		x	x								
Group 2/5			x	x		x						
Group 2/6	x		x		x							
Group 2/7	x											
Group 2/8	x		x									
Group 2/9	x		x									
Group 2/10	x											
Group 2/11	x		x									
Group 2/12	x				x							
Group 2/13	x		x									
Group 2/14	x		x		x		x					
Group 2/15	x											
Group 2/16	x											
Group 2/17		x										
Group 2/18		x			x							
Group 2/19	x				x							
Group 2/20	x		x									
Group 2/21	x											
Group 2/22					x							
Group 2/23			x				x					
Group 2/24	x		x									
Group 2/25	x		x									
Group 2/26												x
Group 2/27												x
Group 2/28												x
Group 2/29												x
Group 2/30												x

			Tumors In									
Group/Bird	**Emaciation**	**Locomotor/ Paralysis**	**Kidney**	**Spleen**	**Gonads**	**Breast**	**Liver**	**Intestine**	**Heart**	**Ascites**	**Yolk Sac Infection**	**Reason Not Given**
Group 2/31												**x**
Group 4/1	**x**											
Group 4/2	**x**		**x**									
Group 4/3								**x**		**x**		
Group 4/4			**x**		**x**	**x**						
Group 4/5	**x**		**x**				**x**		**x**			
Group 4/6	**x**											
Group 4/7		**x**										
Group 4/8												**x**

Study Type	Efficacy
Pertaining to	vvMDV serotype 1
Study Purpose	Demonstrate efficacy against very virulent Marek's disease
Product Administration	Administered *in ovo* to embryonated eggs at 18-19 days of embryonation
Study Animals	Embryonated eggs divided into 4 groups Group 1 vaccinated with Code 16L1.R0 and challenged Group 2 sham vaccinated and challenged (control) Group 3 sham vaccinated non-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 post vaccination
Interval observed after challenge	Observed daily for 45 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: 35/35 Group 3: 0/35 Group 4: 20/33 Requirements of 9 CFR 113.330(c)(4) & (5) were met. Raw data on attached page
USDA Approval Date	June 12, 2015

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

			Tumors In								
Group/Bird	**Emaciation**	**Locomotor/ Paralysis**	**Kidney**	**Spleen**	**Gonads**	**Breast**	**Liver**	**Heart**	**Skin**	**Depression**	**Reason Not Given**
Group 1/1		x								x	
Group 1/2		x		x			x			x	
Group 1/3		x	x		x	x	x			x	
Group 1/4		x								x	
Group 1/5			x	x			x			x	
Group 1/6	x		x	x	x		x			x	
Group 1/7	x			x			x				
Group 2/1				x			x			x	
Group 2/2				x			x			x	
Group 2/3		x		x				x		x	
Group 2/4		x	x	x			x			x	
Group 2/5	x	x	x	x	x		x			x	
Group 2/6		x					x			x	
Group 2/7				x						x	
Group 2/8			x		x	x				x	
Group 2/9				x			x	x		x	
Group 2/10				x			x			x	
Group 2/11			x	x			x			x	
Group 2/12				x				x		x	
Group 2/13			x	x			x			x	
Group 2/14		x						x		x	
Group 2/15		x	x			x				x	
Group 2/16	x		x	x						x	
Group 2/17	x		x	x			x	x		x	
Group 2/18	x		x	x	x					x	
Group 2/19			x	x			x	x		x	
Group 2/20	x						x			x	
Group 2/21				x		x	x			x	
Group 2/22	x		x	x	x	x	x			x	
Group 2/23		x	x	x	x	x		x		x	
Group 2/24		x	x	x			x			x	
Group 2/25	x		x	x							
Group 2/26			x	x						x	
Group 2/27		x	x	x	x	x	x			x	

			Tumors In								
Group/Bird	Emaciation	Locomotor/ Paralysis	Kidney	Spleen	Gonads	Breast	Liver	Heart	Skin	Depression	Reason Not Given
Group 2/28				x			x			x	
Group 2/29	x			x			x			x	
Group 2/30									x	x	
Group 2/31			x		x					x	
Group 2/32									x	x	
Group 2/33				x			x			x	
Group 2/34		x		x		x	x				
Group 2/35		x	x	x			x				
Group 4/1										x	
Group 4/2		x				x					
Group 4/3	x										
Group 4/4			x							x	
Group 4/5	x	x								x	
Group 4/6		x	x				x			x	
Group 4/7	x									x	
Group 4/8			x		x						
Group 4/9		x									
Group 4/10		x	x	x						x	
Group 4/11		x	x								
Group 4/12		x		x							
Group 4/13		x	x	x			x				
Group 4/14			x		x		x				
Group 4/15		x									
Group 4/16		x	x		x	x		x			
Group 4/17			x		x	x					
Group 4/18						x					
Group 4/19			x		x						
Group 4/20			x	x	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 (0.05 mL) by the in ovo route</td></tr>
<tr><td>Study Animals</td><td>Chickens, 18 to 19 day-old embryos
1/2 were vaccinated by in ovo route and 1/2 kept as controls. 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>
<table>
<tr><th>Location</th><th>Treatment</th><th>Total Placed</th><th>21 Day Mortality</th><th>% Mortality</th><th>% Hatchability</th><th>% Condemnation</th></tr>
<tr><td>1</td><td>In ovo</td><td>16,400</td><td>219</td><td>1.3</td><td>87.2</td><td>0.27</td></tr>
<tr><td>1</td><td>Control</td><td>16,400</td><td>163</td><td>1</td><td>83.2</td><td>0.18</td></tr>
<tr><td>2</td><td>In ovo</td><td>21,000</td><td>282</td><td>1.3</td><td>88.8</td><td>1.14</td></tr>
<tr><td>2</td><td>Control</td><td>21,000</td><td>282</td><td>1.3</td><td>88.1</td><td>1.16</td></tr>
<tr><td>3</td><td>In ovo</td><td>20,000</td><td>369</td><td>1.8</td><td>89.2</td><td>0.48</td></tr>
<tr><td>3</td><td>Control</td><td>20,000</td><td>271</td><td>1.4</td><td>81.6</td><td>0.83</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>May 9, 2016</td></tr>
</table>

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety of product under typical use conditions
Product Administration	1 dose (0.2 mL) by the subcutaneous (SQ) route
Study Animals	Chickens, day-old chicks 1/2 by the subcutaneous route and 1/2 kept as controls. Animals were observed daily for mortality through 21 days after vaccination.
Challenge Description	Not applicable
Interval observed after challenge	Not applicable
Results	

Location	Treatment	Total Placed	21 Day Mortality	% Mortality	% Hatchability	% Condemnation
1	SQ	16,400	196	1.2	N/A	0.14
1	Control	16,400	163	1	83.2	0.18
2	SQ	21,000	303	1.4	N/A	1.11
2	Control	21,000	282	1.3	88.1	1.16
3	SQ	20,000	289	1.4	N/A	1.04
3	Control	20,000	271	1.4	81.6	0.83

N/A = not applicable

No adverse reactions attributable to the vaccine were recorded.

USDA Approval Date	May 9, 2016