

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Merial, Inc.
USDA Vet Biologics Establishment Number	298
Product Code	16N1.R0
True Name	Marek's Disease-Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector
Tradename(s)/Distributor (if different from manufacturer)	Newxxitek HVT+ND - No distributor specified
Date of Compilation Summary	December 22, 2016

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 3
Study Purpose	Demonstrate efficacy against Marek's disease
Product Administration	1 dose (0.05 mL) by <i>in ovo</i> route
Study Animals	Day-old chicks divided into 3 groups
	Group 1 vaccinated with Code 16N1.R0 and challenged Group 2 sham vaccinated and challenged (control) Group 3 sham vaccinated non-challenged (control)
Challenge Description	Serotype-1 (SR-1) GA 22 strain given 7 days after vaccination
Interval observed after	The birds were observed daily for clinical signs for 7 weeks.
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)(4) & (5). Birds with clinical signs and/or observable lesions: Group 1: 5/35 Group 2: 29/34 Group 3: 0/34 Requirements of 9 CFR 113.330(c)(4) & (5) were met. Raw data on attached page
USDA Approval Date	December 23, 2013

Group/Bird	Paralysis	Locomotive	Emaciation	Depression	Other Clinical Signs
1/1				•	0
1/2				Х	
1/3					
1/4					
1/5					
2/1		Х			
2/2		Х		Х	
2/3				Х	
2/4				Х	
2/5		Х			
2/6				Х	
2/7				Х	
2/8				Х	
2/9		Х			
2/10					
2/11		Х			
2/12				Х	
2/13				Х	
2/14				Х	
2/15			Х	Х	
2/16				Х	
2/17				Х	
2/18		Х			
2/19				Х	
2/20				Х	
2/21				Х	
2/22				Х	
2/23				Х	
2/24		Х			
2/25				Х	
2/26			Х	Х	
2/27				Х	
2/28		Х			
2/29		Х		Х	

Crown/Dird	Liver	Salaan	Heart	Mussla	Canada	Kidnovo	Other Gross	Commente
Group/Bird	Liver	Spieen	Heart	Muscie	Gonads	Kianeys	Lesions	Comments
1/1				~	X	X		
1/2	v				X			
1/3	~	X			V			
1/4	v	X			X	V		
1/5	~	~		×	~			
2/1	V	X	V	~				
2/2	X	X	X			X		
2/3						X		
2/4		X			X			
2/5						X		
2/6						X		
2/7		X		X	Х			
2/8	Х	X						
2/9				X				
2/10					Х	Х		
2/11	Х	Х		X	Х	Х		
2/12	Х	Х	Х					
2/13		Х	Х					
2/14		Х						
2/15						Х		
2/16				Х	Х	Х		
2/17	Х	Х				Х		
2/18		Х		Х	Х	Х		
2/19		Х	Х					
2/20	Х	Х	Х					
2/21	Х	Х						
2/22	Х	Х				Х		
2/23	Х	Х			Х			
2/24		Х	Х	Х	Х	Х		
2/25		Х	Х					
2/26						Х		
2/27	Х	Х	Х			Х		
2/28						Х		
2/29				Х		Х		

Study Type	Efficacy
Pertaining to	Marek's Disease Virus Serotye 3
Study Purpose	Demonstrate efficacy against Marek's disease
Product Administration	1 dose (0.2 mL) by subcutaneous route
Study Animals	Day-old chicks divided into 3 groups
	Group 1 vaccinated with Code 16N1.R0 and challenged Group 2 sham vaccinated and challenged (control) Group 3 sham vaccinated non-challenged (control)
Challenge Description	Serotype-1 (SR-1) GA 22 strain given 7 days after vaccination
Interval observed after	The birds were observed daily for clinical signs for 7 weeks.
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)(4) & (5). Birds with clinical signs and/or observable lesions: Group 1: 5/35 Group 2: 29/35 Group 3: 0/35 Requirements of 9 CFR 113.330(c)(4) & (5) were met. Raw data on attached page
USDA Approval Date	December 23, 2013

Group/Bird	Paralysis	Locomotive	Emaciation	Depression	Other Clinical Signs
1/1	, ,				
1/2					
1/3					
1/4					
1/5					
2/1					
2/2					
2/3					
2/4					
2/5			Х		
2/6		Х			
2/7	Х				
2/8					
2/9		Х			
2/10			Х		
2/11					
2/12					
2/13					
2/14					
2/15					
2/16		Х	Х	Х	
2/17					
2/18				Х	
2/19			Х		
2/20					
2/21			Х		
2/22				Х	
2/23			Х	Х	
2/24			Х		
2/25					
2/26			Х		
2/27		Х			
2/28			Х		
2/29				Х	

							Other Gross	
Group/Bird	Liver	Spleen	Heart	Muscle	Gonads	Kidneys	Lesions	Comments
1/1	Х					Х		
1/2				Х				
1/3		Х		Х				
1/4	Х	Х			Х	Х		
1/5				Х	Х			
2/1	Х	Х	Х			Х		
2/2		Х				Х		
2/3		Х			Х	Х		
2/4	Х	Х	Х		Х	Х	Х	Skin
2/5	Х	Х			Х	Х		
2/6	Х	Х			Х	Х		
2/7	Х	Х		Х	Х		Х	other = nerve and skin
2/8		Х			Х			
2/9	Х	Х				Х	Х	Skin positive, and GI/proventriculus
2/10	Х	Х						
2/11	Х			Х			Х	GI
2/12	Х					Х		
2/13		Х			Х	Х		
2/14		Х			Х			
2/15	Х							Spleen enlarged
2/16	Х	Х				Х		
2/17		Х						
2/18						Х	Х	Skin positive
2/19	Х	Х			Х	Х		
2/20	Х	Х				Х		
2/21	Х	Х						
2/22	Х							
2/23	Х	Х		Х	Х		Х	other = skin
2/24	Х	Х	Х			Х		
2/25	Х						Х	GI tract
2/26	Х				Х	Х		
2/27								
2/28	Х	Х		x		Х	Х	Skin positive
2/29	Х					Х	Х	Skin, wattles positive, also swollen head

Study Type	Efficacy							
Pertaining to	Newcastle disease virus							
Study Purpose	Demonstrate efficacy against Newcastle disease							
Product Administration	1 dose (0.05 mL) by <i>in ovo</i> route							
Study Animals	Day-old chicks divided into 2 groups							
	Group 1 vaccinated with Code 16N1.R0 and challenged Group 2 sham vaccinated and challenged (control)							
Challenge Description	NDV Texas GB given 28 days after vaccination							
Interval observed after	Birds observed daily for clinical signs for 14 days post challenge							
Results								
Kesuits	Vaccinates and controls were evaluated in terms of Newcastle disease clinical signs per the criteria in 9 CFR 113.329(c)(4). Birds with clinical signs: Group 1: 0/30 Group 2: 29/29 Requirements of 9 CFR 113.329(c)(4) were met. Raw data on attached page							
USDA Approval Date	August 23, 2012							

Croupbind Distress Paralysis Forticollis Signs Tremors Opistholonios Death 2/1 ×	Crown (Dird	Respiratory	Develueia	Terticollie	Other Clinical	Muscular	Oniothotonoo	Death
2/2	Group/Bira	Distress	Paralysis	TOTTICOIIIS	Signs	Tremors	Opistnotonos	Death
2/2	2/1							
2/3	2/2							
2/4 X X X 2/5 X X X 2/6 X X X 2/7 X X X 2/8 X X X 2/9 X X X 2/10 X X X 2/11 X X X 2/12 X X X 2/13 X X X 2/14 X X X 2/17 X X X 2/18 X X X 2/14 X X X 2/17 X X X 2/18 X X X 2/19 X X X 2/17 X X X 2/18 X X X 2/20 X 2/21 X 2/22 X 2/23	2/3		v			v		^
2/3 A A A 2/6 X X X 2/7 X X X 2/8 X X X 2/9 X X X 2/10 X X X 2/10 X X X 2/11 X X X 2/12 X X X 2/13 X X X 2/14 X X X 2/15 X X X 2/16 X X X 2/17 X X X 2/18 X X X 2/19 X X X 2/12 X X X 2/13 X X X 2/20 X X X 2/21 X X X 2/22 X X X 2/23 X X X 2/24 X X </td <td>2/4</td> <td></td> <td>^ </td> <td></td> <td></td> <td>^ </td> <td></td> <td></td>	2/4		^ 			^ 		
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2/20 X 2/21 X 2/22 X 2/23 X 2/24 X 2/25 X 2/26 X X X 2/27 X X X 2/28 X	2/19		^			^		v
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2/22 X X 2/23 X X 2/24 X X 2/25 X X 2/26 X X 2/27 X X 2/28 X X	2/21							
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	2/22							X
2/25 X X 2/26 X X 2/27 X X 2/28 X X	2/23		Y			Y		~
2/26 X X 2/27 X X 2/28 X X	2/24		X			X		
2/27 X X 2/28 X X	2/26		x x			× ×		
2/28 X X	2/27		× ×					
	2/28		x x			× ×		
2/29 X X	2/29		X			X X		

Study Type	Efficacy
Pertaining to	Newcastle disease virus
Study Purpose	Demonstrate efficacy against Newcastle disease
Product Administration	1 dose (0.2 mL) by Subcutaneous route
Study Animals	Day-old chicks divided into 2 groups
	Group 1 vaccinated with Code 16N1.R0 and challenged Group 2 sham vaccinated and challenged (control)
Challenge Description	NDV Texas GB given 28 days after vaccination
Interval observed after	Birds observed daily for clinical signs for 14 days post challenge
challenge	
Results	Vaccinates and controls were evaluated in terms of Newcastle disease clinical signs per the criteria in 9 CFR 113.329(c)(4). Birds with clinical signs: Group 1: 1/29 Group 2: 30/30 Requirements of 9 CFR 113.329(c)(4) were met. Raw data on attached page
USDA Approval Date	August 21, 2012

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

Study Type	Safety	Safety									
Pertaining to	ALL										
Study Purpose	Demonstrate safety of product under typical use conditions										
Product	1 dose by either the (0.05 mL) in ovo or (0.2 mL) subcutaneous (SQ) route										
Administration											
Study Animals	Poultry, 18 of 125,506 we route and 13 21 days afte	Poultry, 18 day-old embryos or day-old chicks 125,506 were vaccinated by in ovo route, 41,900 were vaccinated by subcutaneous route and 136,459 kept as controls. Animals were observed daily for mortality through 21 days after vaccination.									
Challenge Description	Not applicat	Not applicable									
Interval observed after	Not applicat	Not applicable									
challenge											
Results											
						%	%				
	Location	LocationTreatmentTotal21 Day%Hatch- abilityCondemnation									
	1	SQ	9,100	135	1.5	N/A	0.18				
	1	In ovo	9,100	126	1.4	86.9	0.06				
	1	Control	16,400	223	1.4	87.4	0.09				
	2 SQ 20,100 307 1.5 N/A										
	2	In ovo	20,000	325	1.6	87.8					
	2	Control	20,000	439	2.2	85.6	N/A				
	3	SQ	12,700	107	0.8	N/A					
	3 In ovo 12,700 145 1.1 90.2 N/A										
	3	Control	16,900	312	1.8	86.7	N/A				
	4 In ovo 55,900 1447 2.6 84.6 0.20										
	4 Control 55,400 1015 1.8 87.6 0.10										
	5	5 In ovo 27,806 423 1.5 89.4 0.21									
	5 Control 27,759 422 1.5 88.7 0.10										
	N/A is not a No adverse	pplicable reactions attr	ibutable to	o the vaccine	e were reco	rded.					

USDA Approval Date June 15, 2016 and November 10, 2016