Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	16N1.R0
True Name	Marek's Disease-Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Poulvac Procerta HVT-ND - No distributor specified
Date of Compilation Summary	October 08, 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 3
Study Purpose	Demonstrate efficacy against Marek's disease
Product Administration	One dose by the *in ovo* route
Study Animals	Chicken eggs at 18 days of embryonation, divided into 3 groups Group 1 vaccinated with product and challenged Group 2 placebo vaccinated and challenged (positive control) Group 3 sham vaccinated non-challenged (negative control)
Challenge Description	GA22 strain given at 5 days of age
Interval observed after challenge	The birds were observed daily for 7 weeks.
Results	Vaccinates and controls were evaluated in terms of Marek's disease grossly observable lesions per the criteria in 9 CFR 113.330(c). Birds with observable lesions: Group 1: 5/30 Group 2: 27/30 Group 3: 0/30 Requirements of 9 CFR 113.330(c) were met. Raw data on attached page
USDA Approval Date	

Group	animal	skin	breast muscle	heart	liver	proventriculus	spleen	gonads	kidney	intestines	pancreas	nerves	thymic atrophy
1	204												
1	213												
1	229												
1	231												
1	232							X					
1	234												
1	236												
1	248						X	X	X				
1	257												
1	259												
1	268												
1	275												
1	281												
1	285												
1	305												
1	308							X				X	
1	311												
1	312												
1	320												
1	322		X		X		X			X			
1	327												
1	330												
1	333												
1	335												
1	340												
1	344												
1	347												
1	350									X			
1	355												
1	358												
2	215			X					X				
2	221			X	X		X						
2	222			X			X			X			
2	223			X				X	X				
2	224			X	X		X		X				
2	228				X		X			X			

Group	animal	skin	breast muscle	heart	liver	proventriculus	spleen	gonads	kidney	intestines	pancreas	nerves	thymic atrophy
2	233			X									X
2	242			X	X			X	X				
2	247			X	X		X		X	X	X		
2	258						X						
2	263								X			X	
2	265	X											
2	271			X	X		X			X			
2	274			X	X		X		X	X			
2	276			X	X	X	X						
2	283												
2	293	X			X								
2	298	X		X	X		X						
2	299	X		X	X		X						
2	319			X			X						
2	324			X	X			X	X				
2	328			X	X		X			X			
2	334												
2	341	X		X	X		X		X				
2	342			X			X						
2	345									X			
2	346												
2	349			X	X		X		X				
2	352			X	X		X		X				
2	353	X		X									
3	202												
3	206												
3	207												
3	208												
3	210												
3	211												
3	218												
3	219												
3	240												
3	245												
3	255												
3	256												

Group	animal	skin	breast muscle	heart	liver	proventriculus	spleen	gonads	kidney	intestines	pancreas	nerves	thymic atrophy
3	260												
3	266												
3	272												
3	278												
3	280												
3	287												
3	288												
3	294												
3	297												
3	304												
3	306												
3	314												
3	321												
3	323												
3	326												
3	329												
3	332												
3	339												

Study Type	Efficacy
Pertaining to	Marek's Disease Virus Serotype 3
Study Purpose	Demonstrate efficacy against Marek's disease
Product Administration	One dose by the subcutaneous route
Study Animals	Day-old chicks divided into three groups Group 1 vaccinated with product and challenged Group 2 placebo vaccinated and challenged (positive control) Group 3 sham vaccinated non-challenged (negative control)
Challenge Description	GA 22 strain given at 5 days of age
Interval observed after challenge	The birds were observed daily for 7 weeks then tissues were examined
Results	Vaccinates and controls were evaluated in terms of Marek's disease grossly observable lesions per the criteria in 9 CFR 113.330(c). Birds with observable lesions: Group 1: 6/30 Group 2: 30/30 Group 3: 0/30 Requirements of 9 CFR 113.330(c) were met. Raw data on attached page.
USDA Approval Date	26 February 2019

Treatment group	**Animal ID**	**Tissue Examined "X" indicates tissue has grossly observable lesion due to Marek's disease**														
		eyes	**skin**	**breast muscle**	**heart**	**lung**	**liver**	**proventriculus**	**spleen**	**gonads**	**kidney**	**intestines**	**pancreas**	**nerves**	**thymus**	**thymic atrophy**
1	**601**															
1	**602**									**X**						
1	**612**															
1	**613**															

1	617									X	X					
1	632															
1	641															
1	646															
1	648															
1	655															
1	658			X	X		X		X	X	X					
1	661															
1	671															
1	674															
1	675															
1	679															
1	686															
1	691															
1	699															
1	700				X		X									
1	707									X	X					
1	714															
1	718															
1	721															
1	730															
1	739															
1	749															
1	750													X		
1	751															
1	760															
2	607		X		X		X		X					X		
2	609		X		X		X		X		X					
2	616		X				X		X		X	X		X		
2	622		X		X											
2	624				X		X		X							
2	625		X		X		X		X					X		
2	633						X		X	X	X					
2	650		X		X		X		X		X					
2	654													X		
2	656				X				X		X	X				
2	665				X	X			X		X					
2	667						X									
2	669				X		X		X			X		X		
2	673						X		X	X	X					
2	680						X					X				

2	**689**						**X**		**X**			**X**			**X**	
2	**705**				**X**											
2	**709**				**X**		**X**		**X**		**X**					
2	**716**		**X**		**X**		**X**									
2	**719**				**X**		**X**		**X**		**X**					
2	**720**											**X**	**X**			
2	**723**		**X**						**X**	**X**					**X**	
2	**724**		**X**		**X**						**X**					
2	**727**				**X**											
2	**731**				**X**		**X**	**X**	**X**			**X**				
2	**740**				**X**				**X**	**X**	**X**					
2	**741**				**X**				**X**	**X**				**X**		
2	**746**								**X**		**X**					
2	**754**				**X**				**X**							
2	**758**				**X**					**X**		**X**				
3	**604**															
3	**614**															
3	**620**															
3	**623**															
3	**628**															
3	**631**															
3	**639**															
3	**642**															
3	**644**															
3	**647**															
3	**653**															
3	**660**															
3	**663**															
3	**664**															
3	**677**															
3	**681**															
3	**693**															
3	**694**															
3	**695**															
3	**696**															
3	**702**															
3	**703**															
3	**710**															
3	**713**															
3	**715**															
3	**728**															

3	**742**															
3	**748**															
3	**752**															
3	**756**															

Study Type	Efficacy
Pertaining to	Newcastle disease virus (NDV)
Study Purpose	Demonstrate efficacy against Newcastle Disease
Product Administration	1 dose by subcutaneous route
Study Animals	Day-old chicks divided into 2 groups: Group 1 sham vaccinated and challenged (control) Group 2 vaccinated and challenged
Challenge Description	NDV Texas GB given 28 days after vaccination
Interval observed after challenge	Birds observed daily for clinical signs for 14 days post 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: 40/40 Group 2: 1/38 Requirements of 9 CFR 113.329(c)(4) were met. Raw data on attached page
USDA Approval Date	October 5, 2017

Group	Bird	Clinical Signs and/or Mortality
1	307	X
1	352	X
1	355	X
1	371	X
1	373	X
1	375	X
1	379	X
1	382	X
1	398	X
1	405	X
1	412	X
1	417	X
1	435	X
1	437	X
1	438	X
1	439	X
1	444	X
1	450	X
1	469	X
1	470	X
1	305	X
1	346	X
1	356	X
1	366	X
1	369	X
1	385	X
1	388	X
1	390	X
1	393	X
1	397	X
1	404	X
1	411	X
1	414	X
1	415	X
1	424	X
1	429	X
1	431	X
1	445	X
1	465	X
1	477	X

2	310	
2	312	
2	313	
2	316	
2	325	
2	342	
2	402	
2	407	
2	409	
2	418	
2	436	
2	457	
2	459	
2	473	
2	474	
2	463	
2	350	
2	482	
2	308	
2	314	
2	327	
2	332	
2	336	
2	345	
2	359	
2	372	
2	376	
2	394	
2	403	
2	413	
2	423	
2	449	
2	452	
2	462	X
2	468	
2	481	
2	485	
2	487	

Study Type	Efficacy
Pertaining to	Newcastle disease virus (NDV)
Study Purpose	Demonstrate efficacy against Newcastle Disease
Product Administration	1 dose by *in ovo* route
Study Animals	Embryonated eggs at 18-19 days divided into 2 groups: Group 1 sham vaccinated and challenged (control) Group 2 vaccinated and challenged
Challenge Description	NDV Texas GB given 28 days after vaccination
Interval observed after challenge	Birds observed daily for clinical signs for 14 days post 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: 40/40 Group 2: 3/40 Requirements of 9 CFR 113.329(c)(4) were met. Raw data on attached page
USDA Approval Date	October 4, 2017

Group	Bird	Clinical Signs of NDV and/or Mortality
1	131	X
1	134	X
1	135	X
1	141	X
1	143	X
1	150	X
1	153	X
1	155	X
1	169	X
1	178	X
1	179	X
1	207	X
1	223	X
1	267	X
1	273	X
1	285	X
1	289	X
1	290	X
1	292	X
1	206	X
1	115	X
1	116	X
1	145	X
1	154	X
1	158	X
1	162	X
1	163	X
1	195	X
1	197	X
1	203	X
1	205	X
1	215	X
1	219	X
1	222	X
1	250	X
1	264	X
1	268	X
1	291	X
1	102	X
1	140	X

2	103	
2	106	
2	113	
2	123	
2	161	
2	165	
2	168	
2	175	
2	185	
2	193	
2	204	
2	210	
2	212	
2	213	
2	229	
2	243	
2	255	
2	259	
2	277	
2	281	
2	122	
2	133	X
2	136	
2	144	
2	148	
2	152	
2	156	
2	174	
2	180	
2	188	
2	194	X
2	224	
2	231	
2	233	
2	245	
2	252	X
2	258	
2	269	
2	275	
2	114	

Study Type	Efficacy
Pertaining to	Newcastle disease virus
Study Purpose	Demonstrate duration of immunity against Newcastle Disease
Product Administration	1 dose by *in ovo* route
Study Animals	D0 chicks divided into 2 groups: Group 1 sham vaccinated and challenged (control) Group 2 vaccinated with product and challenged
Challenge Description	NDV Texas GB given 63 days after vaccination
Interval observed after challenge	Birds observed daily for clinical signs for 14 days post 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, including mortality: Group 1: 30/30 Group 2: 0/30 Requirements of 9 CFR 113.329(c)(4) were met. Raw data on attached page
USDA Approval Date	06AUG19

		Clinical Signs of NDV		
Group	**Bird**	**Paralysis**	**Respiratory**	**Mortality**
1	104	X	X	
1	111	X	X	
1	127	X	X	
1	152	X	X	
1	178	X	X	
1	186	X	X	
1	200	X	X	
1	204	X	X	
1	208	X	X	
1	229	X	X	
1	238	X	X	
1	290	X	X	
1	294	X	X	
1	295	X	X	
1	332			X
1	134	X	X	
1	139			X
1	144	X	X	
1	154	X	X	
1	188	X	X	

1	191	X	X	
1	212			X
1	218	X	X	
1	232			X
1	239	X	X	
1	251	X	X	
1	275			X
1	299	X	X	
1	319	X	X	
1	322			X
2	132			
2	146			
2	170			
2	189			
2	211			
2	220			
2	225			
2	228			
2	244			
2	245			
2	254			
2	262			
2	271			
2	281			
2	315			
2	156			
2	166			
2	168			
2	187			
2	190			
2	194			
2	217			
2	261			
2	272			
2	273			
2	278			
2	296			
2	316			
2	323			
2	338			

Study Type	Efficacy
Pertaining to	Newcastle disease virus
Study Purpose	Demonstrate duration of immunity against Newcastle Disease
Product Administration	1 dose by the subcutaneous route
Study Animals	D0 chicks divided into 2 groups: Group 1 sham vaccinated and challenged (control) Group 2 vaccinated with product and challenged
Challenge Description	NDV Texas GB given 63 days after vaccination
Interval observed after challenge	Birds observed daily for clinical signs for 14 days post 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, including mortality: Group 1: 30/30 Group 2: 0/30 Requirements of 9 CFR 113.329(c)(4) were met. Raw data on attached page
USDA Approval Date	06AUG19

		Clinical Signs of NDV		
Group	**Bird**	**Paralysis**	**Respiratory**	**Mortality**
1	104	X	X	
1	111	X	X	
1	127	X	X	
1	152	X	X	
1	178	X	X	
1	186	X	X	
1	200	X	X	
1	204	X	X	
1	208	X	X	
1	229	X	X	
1	238	X	X	
1	290	X	X	
1	294	X	X	
1	295	X	X	
1	332			X
1	134	X	X	
1	139			X
1	144	X	X	
1	154	X	X	
1	188	X	X	

1	191	X	X	
1	212			X
1	218	X	X	
1	232			X
1	239	X	X	
1	251	X	X	
1	275			X
1	299	X	X	
1	319	X	X	
1	322			X
2	110			
2	114			
2	115			
2	129			
2	137			
2	198			
2	201			
2	202			
2	242			
2	249			
2	250			
2	253			
2	270			
2	292			
2	327			
2	122			
2	135			
2	141			
2	143			
2	193			
2	195			
2	230			
2	243			
2	256			
2	266			
2	268			
2	269			
2	287			
2	324			
2	340			

<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>One dose administered in ovo (IO) or subcutaneously (SC) at hatch.</td></tr>
<tr><td>Study Animals</td><td>Approximately 175,698 commercial broilers:
Site A: Vaccinates: 20,300, Controls: 20,300
Site B: Vaccinates: 24,000, Controls: 24,000
Site C: Vaccinates: 21,500, Controls: 21,995
Site D: Vaccinates: 21,500, Controls: 22,103</td></tr>
<tr><td>Challenge Description</td><td>Not applicable (NA)</td></tr>
<tr><td>Interval observed after challenge</td><td>Not applicable</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th>Description</th><th>Site</th><th>Route</th><th>Percent Hatchability</th><th>Total Placed</th><th>Percent Mortality</th><th>Condemnation Rates (%) at Processing</th></tr>
<tr><td rowspan="4">Vaccinates</td><td>A</td><td>IO</td><td>96.84</td><td>20,300</td><td>2.78</td><td>0.02</td></tr>
<tr><td>B</td><td>IO</td><td>95.01</td><td>24,000</td><td>2.96</td><td>0.21</td></tr>
<tr><td>C</td><td>SC</td><td>NA</td><td>21,500</td><td>1.75</td><td>1.19</td></tr>
<tr><td>D</td><td>SC</td><td>NA</td><td>21,500</td><td>1.75</td><td>1.06</td></tr>
<tr><td rowspan="4">Controls</td><td>A</td><td>IO</td><td>97.22</td><td>20,300</td><td>2.97</td><td>0.06</td></tr>
<tr><td>B</td><td>IO</td><td>94.82</td><td>24,000</td><td>2.95</td><td>0.97</td></tr>
<tr><td>C</td><td>SC</td><td>NA</td><td>21,995</td><td>2.06</td><td>1.06</td></tr>
<tr><td>D</td><td>SC</td><td>NA</td><td>22,103</td><td>1.76</td><td>1.40</td></tr>
</table>
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<tr><td>USDA Approval Date</td><td>28 August 2019</td></tr>
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