Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	1A88.R3
True Name	Bursal Disease-Marek's Disease Vaccine, Serotype 3, Live Marek's Disease Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Poulvac Procerta HVT-IBD - No distributor specified
Date of Compilation Summary	December 07, 2020

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 (IBDV)
Study Purpose	Demonstrate efficacy against Infectious Bursal disease
Product Administration	One dose by the subcutaneous route
Study Animals	Day-old chicks divided into 3 groups Group 1 vaccinated with product and challenged Group 2 placebo vaccinated and challenged (positive control) Group 3 placebo vaccinated non-challenged (negative control)
Challenge Description	USDA STD strain given at 34 days of age
Interval observed after challenge	The birds were observed daily for 4 days then tissues were examined.
Results	Vaccines and controls were evaluated in terms of Infectious Bursal disease grossly observable lesions per the criteria in 9 CFR 113.331(c). Birds with grossly observable lesions: Group 1: 0/30 Group 2: 30/30 Group 3: 0/29 Requirements of 9 CFR 113.331(c) were met. Raw data on attached page
USDA Approval Date	21 September 2018

Group	Animal	Normal	Edema
1	207	X	
1	221	X	
1	224	X	
1	225	X	
1	237	X	
1	276	X	
1	287	X	
1	289	X	
1	309	X	
1	310	X	
1	321	X	
1	341	X	
1	342	X	
1	344	X	
1	329	X	

Group	Animal	Normal	Edema
1	212	X	
1	219	X	
1	226	X	
1	238	X	
1	244	X	
1	251	X	
1	253	X	
1	266	X	
1	267	X	
1	281	X	
1	282	X	
1	292	X	
1	293	X	
1	319	X	
1	330	X	
2	211		X
2	216		X
2	223		X
2	228		X
2	243		X
2	245		X
2	247		X
2	275		X
2	279		X
2	291		X
2	296		X
2	313		X
2	320		X
2	336		X
2	337		X
2	220		X
2	229		X
2	233		X
2	248		X
2	249		X
2	258		X
2	270		X
2	273		X
2	284		X
2	288		X

Group	Animal	Normal	Edema
2	290		X
2	307		X
2	325		X
2	334		X
2	335		X
3	202	X	
3	217	X	
3	257	X	
3	269	X	
3	277	X	
3	305	X	
3	306	X	
3	308	X	
3	315	X	
3	316	X	
3	322	X	
3	333	X	
3	340	X	
3	259	X	
3	232	X	
3	241	X	
3	242	X	
3	250	X	
3	252	X	
3	262	X	
3	265	X	
3	271	X	
3	297	X	
3	303	X	
3	312	X	
3	318	X	
3	324	X	
3	338	X	
3	209	X	

Study Type	Efficacy
Pertaining to	Infectious Bursal Disease Virus (IBDV)
Study Purpose	Demonstrate efficacy against infectious bursal disease
Product Administration	One dose by the *in ovo* route to 18-day-old embryonated chicken eggs
Study Animals	E18 eggs divided into 3 groups Group 1 vaccinated with product and challenged Group 2 placebo vaccinated and challenged (positive control) Group 3 non-vaccinated non-challenged (negative control)
Challenge Description	USDA STD IBDV given at 34 days of age
Interval observed after challenge	The birds were observed daily for 4 days and then tissues examined.
Results	Vaccinates and controls were evaluated in terms of infectious bursal disease gross acute lesions per the criteria in 9 CFR 113.331(c). Birds with observable lesions: Group 1: 0/30 Group 2: 30/30 Group 3: 0/29 Requirements of 9 CFR 113.331(c) were met. Raw data on attached page
USDA Approval Date	20 September 2018

Group	Animal	Normal	Edema	Edema and Hemorrhage
1	601	X		
1	604	X		
1	612	X		
1	621	X		
1	629	X		
1	633	X		
1	639	X		
1	642	X		
1	648	X		
1	652	X		
1	662	X		
1	665	X		
1	674	X		

1	677	X		
1	686	X		
1	689	X		
1	691	X		
1	692	X		
1	695	X		
1	697	X		
1	707	X		
1	709	X		
1	714	X		
1	716	X		
1	720	X		
1	722	X		
1	724	X		
1	725	X		
1	730	X		
1	744	X		
2	607		X	
2	622		X	
2	625			X
2	628		X	
2	630		X	
2	635		X	
2	638		X	
2	640		X	
2	643		X	
2	644		X	
2	645		X	
2	647		X	
2	658		X	
2	661		X	
2	664		X	
2	673		X	
2	683		X	
2	688		X	
2	690		X	
2	693		X	
2	703		X	
2	704		X	
2	705		X	
2	708		X	
2	713		X	
2	728		X	

2	729			X
2	734		X	
2	737		X	
2	739		X	
3	606	X		
3	609	X		
3	613	X		
3	620	X		
3	634	X		
3	637	X		
3	649	X		
3	650	X		
3	653	X		
3	655	X		
3	656	X		
3	666	X		
3	669	X		
3	671	X		
3	676	X		
3	684	X		
3	687	X		
3	696	X		
3	700	X		
3	701	X		
3	706	X		
3	711	X		
3	715	X		
3	726	X		
3	727	X		
3	733	X		
3	736	X		
3	738	X		
3	741	X		

Study Type	Efficacy
Pertaining to	Infectious Bursal Disease Virus
Study Purpose	Demonstrate efficacy against Standard Infectious Bursal disease 63 days post vaccination
Product Administration	1 dose by *in ovo* route
Study Animals	Treatment groups: Group 1 vaccinated *in ovo* at 18 days of embryonation with product and challenged Group 2 placebo vaccinated SQ at day-of-age and challenged (positive control) Group 3 placebo vaccinated SQ at day-of-age and not challenged (negative control)
Challenge Description	USDA STD IBDV given 63 days after vaccination
Interval observed after challenge	Birds observed daily for 4 days
Results	Vaccinates and controls were evaluated in terms of Infectious Bursal Disease gross bursal lesions per criteria in 9 CFR 113.331(b)(2)(i). Birds with grossly observable lesions: Group 1: 0/30 Group 2: 30/30 Group 3: 0/28 Requirements of 9 CFR 113.331(b)(2)(i) were met. Raw data on attached page.
USDA Approval Date	January 6, 2020

Group	Animal	Normal	Edema
1	103	X	
1	135	X	
1	161	X	
1	164	X	
1	171	X	
1	174	X	
1	183	X	
1	184	X	
1	204	X	
1	214	X	
1	220	X	
1	223	X	
1	226	X	
1	230	X	
1	233	X	

1	236	X	
1	237	X	
1	242	X	
1	246	X	
1	252	X	
1	253	X	
1	256	X	
1	263	X	
1	286	X	
1	290	X	
1	314	X	
1	319	X	
1	330	X	
1	335	X	
1	337	X	
2	115		X
2	123		X
2	132		X
2	133		X
2	134		X
2	141		X
2	144		X
2	153		X
2	159		X
2	165		X
2	172		X
2	188		X
2	194		X
2	213		X
2	225		X
2	229		X
2	249		X
2	264		X
2	266		X
2	273		X
2	281		X
2	283		X
2	289		X
2	301		X
2	303		X
2	312		X
2	315		X
2	318		X
2	320		X

2	323		X
3	116	X	
3	117	X	
3	119	X	
3	120	X	
3	140	X	
3	145	X	
3	150	X	
3	152	X	
3	157	X	
3	176	X	
3	180	X	
3	181	X	
3	210	X	
3	212	X	
3	234	X	
3	258	X	
3	260	X	
3	267	X	
3	272	X	
3	279	X	
3	280	X	
3	285	X	
3	288	X	
3	297	X	
3	308	X	
3	325	X	
3	333	X	
3	334	X	

Study Type	Efficacy
Pertaining to	Infectious Bursal Disease Virus
Study Purpose	Demonstrate efficacy against Standard Infectious Bursal disease 63 days post vaccination
Product Administration	1 dose by the subcutaneous (SQ) route
Study Animals	Treatment groups at day-of-age: Group 1 vaccinated SQ with product and challenged Group 2 placebo vaccinated SQ and challenged (control) Group 3 placebo vaccinated SQ and not challenged (control)
Challenge Description	USDA STD IBDV given 63 days after vaccination
Interval observed after challenge	Birds observed daily for 4 days
Results	Vaccinates and controls were evaluated in terms of Infectious Bursal Disease gross bursal lesions per criteria in 9 CFR 113.331(b)(2)(i). Birds with grossly observable lesions: Group 1: 0/25 Group 2: 30/30 Group 3: 0/28 Requirements of 9 CFR 113.331(b)(2)(i) were met. Raw data on attached page.
USDA Approval Date	January 6, 2020

Group	Animal	Normal	Edema
1	102	X	
1	112	X	
1	124	X	
1	163	X	
1	169	X	
1	185	X	
1	197	X	
1	199	X	
1	202	X	
1	207	X	
1	209	X	
1	218	X	
1	224	X	
1	228	X	
1	231	X	
1	238	X	
1	265	X	
1	270	X	

1	275	X	
1	282	X	
1	287	X	
1	293	X	
1	304	X	
1	322	X	
1	336	X	
2	115		X
2	123		X
2	132		X
2	133		X
2	134		X
2	141		X
2	144		X
2	153		X
2	159		X
2	165		X
2	172		X
2	188		X
2	194		X
2	213		X
2	225		X
2	229		X
2	249		X
2	264		X
2	266		X
2	273		X
2	281		X
2	283		X
2	289		X
2	301		X
2	303		X
2	312		X
2	315		X
2	318		X
2	320		X
2	323		X
3	116	X	
3	117	X	
3	119	X	
3	120	X	
3	140	X	
3	145	X	
3	150	X	

3	152	X	
3	157	X	
3	176	X	
3	180	X	
3	181	X	
3	210	X	
3	212	X	
3	234	X	
3	258	X	
3	260	X	
3	267	X	
3	272	X	
3	279	X	
3	280	X	
3	285	X	
3	288	X	
3	297	X	
3	308	X	
3	325	X	
3	333	X	
3	334	X	

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	Eggs at 18 days of embryonation divided into three groups Group 1 vaccinated with product and challenged Group 2 placebo vaccinated and challenged (challenge control) Group 3 sham vaccinated non-challenged (nonchallenge control)
Challenge Description	GA 22 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: 26/30 Group 3: 0/30 Requirements of 9 CFR 113.330(c) were met. Raw data on attached pages.
USDA Approval Date	7 September 2018

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	407			X						X						
1	411															
1	412															
1	414															
1	417															
1	420															
1	424															
1	429															
1	434															
1	436															
1	438								X		X	X				
1	442															
1	458															
1	466															
1	468															
1	469															
1	481									X		X	X	X		
1	482															
1	485															
1	487													X		
1	490															
1	493															
1	494															
1	505															
1	518															
1	520															
1	528															
1	530															
1	543															

1	**551**									**X**		**X**		**X**		
2	**403**				**X**		**X**				**X**					
2	**404**				**X**		**X**		**X**	**X**						
2	**408**				**X**					**X**						
2	**409**	**X**			**X**											
2	**419**		**X**	**X**	**X**	**X**	**X**				**X**					
2	**423**		**X**		**X**		**X**		**X**					**X**		
2	**440**		**X**		**X**						**X**					
2	**448**															
2	**450**		**X**		**X**											
2	**452**		**X**								**X**					
2	**454**				**X**		**X**							**X**		
2	**456**															
2	**463**				**X**		**X**				**X**					
2	**467**		**X**		**X**		**X**		**X**					**X**		
2	**470**		**X**		**X**	**X**	**X**		**X**							**X**
2	**474**						**X**		**X**							
2	**478**				**X**		**X**		**X**	**X**	**X**	**X**	**X**		**X**	
2	**479**		**X**				**X**		**X**		**X**					
2	**483**											**X**		**X**		
2	**492**				**X**		**X**		**X**			**X**				
2	**495**				**X**		**X**				**X**					
2	**500**				**X**					**X**	**X**					**X**
2	**501**															
2	**506**				**X**		**X**		**X**	**X**						
2	**510**				**X**		**X**		**X**			**X**		**X**		
2	**522**				**X**		**X**				**X**					
2	**539**				**X**		**X**		**X**		**X**	**X**		**X**		
2	**540**				**X**		**X**		**X**		**X**					
2	**549**															
2	**553**						**X**		**X**			**X**				
3	**401**															
3	**405**															
3	**410**															
3	**416**															
3	**422**															
3	**426**															
3	**431**															
3	**432**															
3	**439**															
3	**444**															

3	**459**															
3	**475**															
3	**480**															
3	**484**															
3	**488**															
3	**498**															
3	**502**															
3	**508**															
3	**511**															
3	**512**															
3	**514**															
3	**519**															
3	**521**															
3	**523**															
3	**525**															
3	**527**															
3	**532**															
3	**537**															
3	**545**															
3	**548**															

Study Type	Efficacy
Pertaining to	Marek's Disease Virus (MDV) 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 3 groups Group 1 vaccinated with Code product and challenged Group 2 placebo vaccinated and challenged (positive control) Group 3 placebo 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: 3/30 Group 2: 25/29 Group 3: 0/27 Requirements of 9 CFR 113.330(c) were met. Thirty birds in Group 2 and Group 3 survived to 5 days of age; birds were excluded from the study for causes unrelated to conduct of the study. Raw data on attached page
USDA Approval Date	18 October 2018

treatment	animal	eyes	skin	breast muscle	heart	liver	proventriculus	spleen	gonads	kidney	intestines	nerves	thymus
1	837												
1	845												
1	849												
1	859					X		X		X	X		
1	860			X		X				X			
1	865												
1	874												
1	875												
1	876												
1	911												
1	926			X					X				
1	946												
1	958												
1	825												
1	895												
1	803												
1	826												
1	847												
1	858												
1	878												
1	882												
1	885												
1	899												
1	901												
1	918												
1	922												
1	923												
1	938												
1	942												
1	956												
2	804					X		X			X		
2	812		X		X	X		X					
2	822		X		X						X		
2	840				X			X		X			
2	868			X					X				

2	**908**		X		X	X		X		X			
2	**912**				X	X		X		X			
2	**913**												
2	**917**			X									
2	**920**												
2	**925**		X		X								
2	**950**				X	X							
2	**953**		X		X	X	X			X			
2	**955**											X	
2	**807**					X		X			X	X	
2	**813**				X			X		X	X		
2	**814**												
2	**828**												
2	**831**									X			
2	**836**		X		X	X		X					
2	**838**				X	X		X		X			
2	**853**		X	X	X	X		X		X			
2	**863**				X	X		X			X		
2	**892**				X	X		X					
2	**897**					X							
2	**909**					X				X			
2	**930**				X	X				X			X
2	**940**				X	X							
2	**954**				X	X		X		X	X		
3	**811**												
3	**827**												
3	**829**												
3	**850**												
3	**854**												
3	**881**												
3	**898**												
3	**907**												
3	**910**												
3	**921**												
3	**924**												
3	**941**												
3	**808**												
3	**809**												
3	**821**												
3	**830**												
3	**833**												

3	**852**												
3	**855**												
3	**861**												
3	**888**												
3	**889**												
3	**900**												
3	**902**												
3	**914**												
3	**936**												
3	**960**												

<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) at days 18-19 of embryonation or subcutaneously (SC) at hatch.</td></tr>
<tr><td>Study Animals</td><td>Approximately 277,257 commercial broilers:
Site A: Vaccinates: 39,000, Controls: 39,000
Site B: Vaccinates: 56,200, Controls: 56,200
Site C: Vaccinates: 21,920, Controls: 21,937
Site D: Vaccinates: 21,500, Controls: 21,500</td></tr>
<tr><td>Challenge Description</td><td>Not applicable (NA)</td></tr>
<tr><td>Interval observed after challenge</td><td>Not applicable. Daily mortality rates determined through 60 days of age.</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 (%)</th></tr>
<tr><td rowspan="4">Vaccinates</td><td>A</td><td>IO</td><td>82.4</td><td>39,000</td><td>5.4</td><td>0.43</td></tr>
<tr><td>B</td><td>IO</td><td>85.2</td><td>56,200</td><td>4.3</td><td>0.04</td></tr>
<tr><td>C</td><td>SC</td><td>NA</td><td>21,920</td><td>3.5</td><td>0.58</td></tr>
<tr><td>D</td><td>SC</td><td>NA</td><td>21,500</td><td>1.4</td><td>0.65</td></tr>
<tr><td rowspan="4">Controls</td><td>A</td><td>IO</td><td>85.4</td><td>39,000</td><td>4.6</td><td>0.39</td></tr>
<tr><td>B</td><td>IO</td><td>85.1</td><td>56,200</td><td>4.2</td><td>0.09</td></tr>
<tr><td>C</td><td>SC</td><td>NA</td><td>21,937</td><td>2.9</td><td>0.58</td></tr>
<tr><td>D</td><td>SC</td><td>NA</td><td>21,500</td><td>2.3</td><td>0.72</td></tr>
</table>
</td></tr>
<tr><td>USDA Approval Date</td><td>December 1, 2020</td></tr>
</table>