

## **Summary of Studies Supporting USDA Product Licensure**

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	1A89.R0
True Name	Bursal Disease-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-IBD-ND - No distributor specified
Date of Compilation Summary	June 22, 2022

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.

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Study Type	Efficacy		
Pertaining to	Infectious Bursal Disease Virus (IBDV)		
Study Purpose	Demonstrate efficacy against Infectious Bursal disease		
Product Administration	One dose by the <i>in ovo</i> 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)		
<b>Challenge Description</b>	USDA STD strain given at 34 days of age		
Interval observed after	The birds were observed daily for 4 days then bursa were		
challenge	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).		
	CTR 113.331(c).		
	Birds with gross observable lesions:		
	Group 1: 0/30		
	Group 2: 28/30		
	Group 3: 0/30		
	Requirements of 9 CFR 113.331(c) were met.		
	Raw data on attached page		
	I0-		
<b>USDA Approval Date</b>	23 April 2020		

## **Evaluation of Bursal Lesions**

Group	Animal	Edema	Edema &
			Hemorrhage
1	210		
1	212		
1	227		
1	228		
1	232		
1	240		
1	246		
1	247		
1	251		
1	253		
1	255		
1	270		
1	272		
1	276		
1	279		

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1	280		
1	282		
1	283		
1	286		
	292		
1	295		
1	301		
1 1 1	303		
1	306		
1	311		
1	315		
1	316		
1	328		
1	332		
1	344		
2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	201	X	
2	204		
2	205	X	
2	207	X	
2	222		X
2	223	X	
2	229		
2	230	X	
2	233	X X X X X	
2	238	X	
2	242	X	
2	243	X	
2	254	X	
2	261	X	
2	263	X	
2	264	X	
2	288	X	
2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	289	X X X X X	
2	304	X	
2	307	X	
2	308	X	
2	317		X
2	318	X	
2	320	X X X X X	
2	323	X	
2	330	X	
2	333	X	
2	336		
	•	•	

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1	1	
340	X	
342	X	
248		
256		
258		
260		
267		
268		
269		
277		
278		
285		
287		
294		
297		
299		
300		
309		
313		
321		
324		
331		
339		
343		
	208 216 217 224 231 236 239 248 256 258 259 260 267 268 269 277 278 285 287 294 297 299 300 309 313 321 324 331 339	342 X 208 216 217 224 231 236 239 248 256 258 259 260 267 268 269 277 278 285 287 294 297 299 300 309 313 321 324 331 339

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Study Type	Efficacy		
Pertaining to	Infectious Bursal Disease Virus (IBDV)		
<b>Study Purpose</b>	Demonstrate efficacy against Infectious Bursal disease		
<b>Product Administration</b>	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	USDA STD IBDV strain given at 34 days of age		
Interval observed after	The birds were observed daily for 4 days then bursa were		
challenge	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: 0/30		
	Requirements of 9 CFR 113.331(c) were met.		
	Raw data on attached page		
LICDA Assessed Ded	24 A 12020		
USDA Approval Date	24 April 2020		

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<b>Evaluation of Bursal Lesions</b>			
Group	Animal	Edema	Edema & Hemorrhage
1	405		8
1	414		
1	415		
1	417		
1	421		
1	428		
1	436		
1	440		
1	443		
1	444		
1	445		
1	446		
1	449		
1	452		
1	457		
1	460		
1	465		
1	468		
1	473		
1	479		
1	492		
1	493		
1	496		
1	504		
1	524		
1	525		
1	527		
1	528		
1	529		
1	534		
2	407	X	
2	409	X	
2	413	X	
2	416	X	
2	420	X	

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	•	ı	
2	423	X	
2	432	X	
2	433	X	
2	437	X	
2	438	X	
2	439	X	
2	447	X	
2	450	X	
2	463	X	
2	467	X	
2	469		X
2	474	X	
2	476	X	
2	480	X	
2	481	X	
2	487	X	
2	488	X	
2	495	X	
2	506	X	
2	509	X	
2	512	X	
2	515	X	
2	542	X	
2	543	X	
2	544	X	
3	401		
3	402		
3	406		
3	412		
3	422		
3	429		
3	430		
	451		
3	454		
3	456		
3	458		
3	459		
3	462 471		
J	4/1		

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3	475	
3	477	
3	484	
3	491	
3	494	
3	500	
3	503	
3	510	
3	513	
3	518	
3	521	
3	535	
3	537	
3	539	
3	540	
3	541	

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Study Type	Efficacy		
Pertaining to	Infectious Bursal Disease Virus (IBDV)		
Study Purpose	Demonstrate effectiveness against infectious bursal disease 63		
	days after vaccination		
<b>Product Administration</b>	One dose by the <i>in ovo</i> route		
Study Animals	Chicken eggs at 18 days of embryonation, divided into 3 groups:		
	Group 1 vaccinated with product <i>in ovo</i> and challenged		
	Group 2 placebo vaccinated and challenged (control)		
	Group 3 placebo vaccinated and not challenged (control)		
<b>Challenge Description</b>	USDA STD strain given at 63 days after vaccination		
Interval observed after	The birds were observed daily for 4 days post-challenge		
challenge			
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 gross observable lesions:		
	Group 1: 0/30		
	Group 2: 28/30		
	Group 3: 0/30		
	Requirements of 9 CFR 113.331(c)(3)(ii) were met.		
	Raw data on attached page		
USDA Approval Date	June 9, 2020		

Group	Animal	Peri- Bursal Edema	Peri-Bursal Edema & Hemorrhage
1	108		
1	112		
1	120		
1	126		
1	134		
1	136		
1	141		
1	143		
1	153		
1	162	-	
1	168		
1	173		

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1       189         1       192         1       214         1       224         1       251         1       259         1       272         1       282         1       294         1       303         1       309         1       314         1       324         1       328         1       333         2       101         X       X         2       110         X       X         2       117         X       X         2       124         X       X         2       135         2       151         X       X         2       160         X       X         2       164         X       X         2       198         X       X         2       250         X       X         2       263         X       X		•		1
1       192         1       214         1       222         1       224         1       251         1       259         1       282         1       294         1       303         1       309         1       314         1       324         1       328         1       333         2       101         X       X         2       110         X       X         2       117         X       X         2       124         X       X         2       135         2       155         X       X         2       160         X       X         2       164         X       X         2       198         X       X         2       208         X       X         2       250         X       X         2       263         X         2       26	1	180		
1       214         1       222         1       251         1       259         1       272         1       282         1       294         1       303         1       309         1       314         1       324         1       328         1       333         2       101         X       X         2       117         X       X         2       124         X       X         2       130         X       X         2       151         X       X         2       155         X       X         2       160         X       X         2       188         X       X         2       196         2       198         X       X         2       250         X       X         2       263         X       X         2       264         X<		189		
1       224         1       251         1       259         1       272         1       282         1       294         1       303         1       309         1       314         1       328         1       333         2       101         2       102         X       2         2       117         X       2         2       130         X       2         2       135         2       151         X       2         2       160         X       2         2       164         X       2         2       193         X       2         2       198         X       2         2       250         X       2         2       263         X       2         2       264         X       2         2       264         X	1	192		
1       224         1       251         1       259         1       272         1       282         1       294         1       303         1       309         1       314         1       328         1       333         2       101         2       102         X       2         2       117         X       2         2       130         X       2         2       135         2       151         X       2         2       160         X       2         2       164         X       2         2       193         X       2         2       198         X       2         2       250         X       2         2       263         X       2         2       264         X       2         2       264         X	1	214		
1       259         1       272         1       282         1       294         1       303         1       314         1       324         1       328         1       333         2       101         X       2         2       110         X       2         2       117         X       2         2       124         X       2         2       135         2       151         X       2         2       155         X       2         2       160         X       2         2       198         X       2         2       198         X       2         2       252         X       2         2       263         X       2         2       264         X       2         2       264         X       2	1	222		
1       259         1       272         1       282         1       294         1       303         1       314         1       324         1       328         1       333         2       101         X       2         2       110         X       2         2       117         X       2         2       124         X       2         2       135         2       151         X       2         2       155         X       2         2       160         X       2         2       198         X       2         2       198         X       2         2       252         X       2         2       263         X       2         2       264         X       2         2       264         X       2	1	224		
1       282         1       294         1       303         1       309         1       314         1       324         1       328         1       333         2       101         X       X         2       110         X       X         2       117         X       X         2       127         X       X         2       135         2       151         X       X         2       155         X       X         2       160         X       X         2       164         X       X         2       198         X       X         2       198         X       X         2       208         X       X         2       250         X       X         2       263         X       X	1	251		
1       282         1       294         1       303         1       309         1       314         1       324         1       328         1       333         2       101         X       X         2       110         X       X         2       117         X       X         2       127         X       X         2       135         2       151         X       X         2       155         X       X         2       160         X       X         2       164         X       X         2       198         X       X         2       198         X       X         2       208         X       X         2       250         X       X         2       263         X       X	1	259		
1       294         1       303         1       309         1       314         1       324         1       328         1       333         2       101       X         2       110       X         2       117       X         2       124       X         2       130       X         2       135       X         2       151       X         2       155       X         2       160       X         2       164       X         2       198       X         2       198       X         2       208       X         2       208       X         2       250       X         2       263       X         2       264       X         2       287       X		272		
1       294         1       303         1       309         1       314         1       328         1       333         2       101         X       X         2       110         X       X         2       117         X       X         2       124         X       X         2       135         2       151         X       X         2       155         X       X         2       160         X       X         2       164         X       X         2       198         X       X         2       198         X       X         2       208         X       X         2       250         X       X         2       263         X       X	1	282		
1       303         1       314         1       324         1       328         1       333         2       101         X       X         2       110         X       X         2       117         X       X         2       124         X       X         2       130         X       X         2       151         X       X         2       155         X       X         2       160         X       X         2       188         X       X         2       193         X       X         2       198         X       X         2       208         X       X         2       250         X         2       263         X         2       264         X		291		
1       309         1       314         1       324         1       328         1       333         2       101         X       X         2       110         X       X         2       117         X       X         2       124         X       X         2       135         2       151         X       X         2       155         X       X         2       160         X       X         2       164         X       X         2       198         X       X         2       198         X       X         2       208         X       X         2       250         X       X         2       263         X       X         2       264         X       X	1	294		
1       314         1       324         1       328         1       333         2       101         X       X         2       110         X       X         2       117         X       X         2       124         X       X         2       130         X       X         2       135         2       151         X       X         2       160         X       X         2       164         X       X         2       198         X       X         2       198         X       X         2       208         X       X         2       250         X       X         2       263         X         2       264         X         2       271         X		303		
1       324         1       328         1       333         2       101         2       102         X       X         2       117         X       X         2       124         X       X         2       130         X       X         2       135         2       151         X       X         2       160         X       X         2       164         X       X         2       198         X       X         2       198         X       X         2       208         X       X         2       250         X       X         2       252         X       X         2       263         X         2       264         X	1	309		
1       328         1       333         2       101         2       102         X       X         2       110         X       X         2       124         X       X         2       130         X       X         2       135         2       151         X       X         2       155         X       X         2       164         X       X         2       188         X       X         2       198         X       X         2       198         X       X         2       250         X       X         2       252         X       X         2       264         X       X	1	314		
2 188 X 2 193 X 2 196  2 198 X 2 208 X 2 217 X 2 250 X 2 252 X 2 263 X 2 264 X 2 287 X	1	324		
2 188 X 2 193 X 2 196  2 198 X 2 208 X 2 217 X 2 250 X 2 252 X 2 263 X 2 264 X 2 287 X	1	328		
2 188 X 2 193 X 2 196  2 198 X 2 208 X 2 217 X 2 250 X 2 252 X 2 263 X 2 264 X 2 287 X	1	333		
2 188 X 2 193 X 2 196  2 198 X 2 208 X 2 217 X 2 250 X 2 252 X 2 263 X 2 264 X 2 287 X	2	101		
2 188 X 2 193 X 2 196  2 198 X 2 208 X 2 217 X 2 250 X 2 252 X 2 263 X 2 264 X 2 287 X	2	102	X	
2 188 X 2 193 X 2 196  2 198 X 2 208 X 2 217 X 2 250 X 2 252 X 2 263 X 2 264 X 2 287 X	2	110	X	
2 188 X 2 193 X 2 196  2 198 X 2 208 X 2 217 X 2 250 X 2 252 X 2 263 X 2 264 X 2 287 X	2	117		X
2 188 X 2 193 X 2 196  2 198 X 2 208 X 2 217 X 2 250 X 2 252 X 2 263 X 2 264 X 2 287 X	2	124		
2 188 X 2 193 X 2 196  2 198 X 2 208 X 2 217 X 2 250 X 2 252 X 2 263 X 2 264 X 2 287 X	2	127	X	
2 188 X 2 193 X 2 196  2 198 X 2 208 X 2 217 X 2 250 X 2 252 X 2 263 X 2 264 X 2 287 X	2	130		X
2 188 X 2 193 X 2 196  2 198 X 2 208 X 2 217 X 2 250 X 2 252 X 2 263 X 2 264 X 2 287 X	2	135		
2 188 X 2 193 X 2 196  2 198 X 2 208 X 2 217 X 2 250 X 2 252 X 2 263 X 2 264 X 2 287 X	2	151	X	
2 188 X 2 193 X 2 196  2 198 X 2 208 X 2 217 X 2 250 X 2 252 X 2 263 X 2 264 X 2 287 X	2	155	X	
2 188 X 2 193 X 2 196  2 198 X 2 208 X 2 217 X 2 250 X 2 252 X 2 263 X 2 264 X 2 287 X	2	160	X	
2 193 X 2 196 2 198 X 2 208 X 2 217 X 2 250 X 2 252 X 2 263 X 2 264 X 2 287 X	2	164		X
2 196 2 198 X 2 208 X 2 217 X 2 250 X 2 252 X 2 263 X 2 264 X 2 271 X 2 287 X	2	188	X	
2 198 X 2 208 X 2 217 X 2 250 X 2 252 X 2 263 X 2 264 X 2 271 X 2 287 X		193	X	
2 208 X 2 217 X 2 250 X 2 252 X 2 263 X 2 264 X 2 271 X	2	196		
2 208 X 2 217 X 2 250 X 2 252 X 2 263 X 2 264 X 2 271 X	2	198	X	
2 217 X 2 250 X 2 252 X 2 263 X 2 264 X 2 271 X	2		X	
2 250 X 2 252 X 2 263 X 2 264 X 2 271 X	2		$\mathbf{X}$	
2 252 X 2 263 X 2 264 X 2 271 X 2 287 X	2		$\mathbf{X}$	
2 264 <b>X</b> 2 271 <b>X</b> 2 287 <b>X</b>	2	l	$\mathbf{X}$	
2 264 X 2 271 X 2 287 X	2		X	
2 271 <b>X</b> 287 <b>X</b>	2	l	X	
2 287 <b>X</b>	2			
, , , , , , , , , , , , , , , , , , , ,		271	2 <b>%</b>	
2 288 X	2	271 287	2 %	X

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	1	1	
2	307	X	
2	308	X	
2	323		X X
2	329		X
2	338	X	
3	123		
3	133		
3	138		
3	145		
3	149		
3	152		
3	156		
3	169		
3	172		
3	174		
3	183		
3	201		
3	202		
3	204		
3	216		
3	223		
3	239		
3	246		
3	261		
3	267		
3	276		
3	279		
3	285		
2 2 2 2 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	292		
3	310		
3	320		
3	327		
3	335		
3 3 3 3	339		
3	340		

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Study Type	Efficacy
Pertaining to	Infectious Bursal Disease Virus (IBDV)
Study Purpose	Demonstrate effectiveness against infectious bursal disease 63
	days after vaccination
<b>Product Administration</b>	One dose by the subcutaneous route
Study Animals	Day old chicks divided into 3 groups:
	Group 1 vaccinated with product subcutaneously and challenged
	Group 2 placebo vaccinated and challenged (control)
	Group 3 placebo vaccinated and not challenged (control)
<b>Challenge Description</b>	USDA STD strain given at 63 days after vaccination
Interval observed after	The birds were observed daily for 4 days post-challenge
challenge	
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 gross observable lesions:
	Group 1: 0/30
	Group 2: 28/30
	Group 3: 0/30
	Requirements of 9 CFR 113.331(c)(3)(3)(ii) were met.
	Raw data on attached page
	X 0.000
USDA Approval Date	June 9, 2020

Group	Animal	Peri- Bursal Edema	Peri-Bursal Edema & Hemorrhage
1	105		
1	106		
1	122		
1	140		
1	142		
1	148		
1	161		
1	171		
1	190		
1	203		
1	207		
1	215		

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		1	1
1	226		
1	231		
1	237		
1	243		
1	244		
1	254		
1	257		
1	265		
1	266		
1	273		
1	283		
1	293		
1	295		
1	296		
1	299		
1	300		
1	325		
1	331		
2	101	X	
2	102	X	
2	110	X	
1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	117		X
2	124	X	
2	127	X	
2	130		X
2	135		
2	151	X	
2	155	X	
2	160	X	
2	164		X
	188	X	
2	193	X	
2	196		
2 2 2 2 2 2 2 2 2 2 2 2	198	X	
2	208	X X X X X	
2	217	X	
2	250	X	
2	252	X	
2	263	X	
2	264	X	
2	271	X	
2	287		X
2	288	X	

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2	307	X		
2	308	X		
2	323		X	
2	329		X	
2	338	X		
3	123			
2 2 2 2 2 3 3 3	133			
3	138			
3	145			
3 3 3 3	149			
3	152			
	156			
3	169			
3	172			
3	174			
3	183			
3 3 3 3 3 3 3 3 3 3 3 3	201			
3	202			
3	204			
3	216			
3	223			
3	239			
3	246			
3	261			
3	267			
3	276			
3	279			
3	285			
3	292			
3	310			
3	320			
3	327			
3	335			
3	339			
3	340			
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Study Type	Efficacy
Pertaining to	Marek's Disease Virus Serotype 3
Study Purpose	Demonstrate efficacy against Marek's Disease
<b>Product Administration</b>	One dose by the <i>in ovo</i> 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 placebo vaccinated non-challenged (negative control)
<b>Challenge Description</b>	GA 22 strain given at 5 days of age.
Interval observed after	The birds were observed daily for 49 days.
challenge	
Results	Vaccines and controls were evaluated in terms of Marek's
	disease grossly observable lesions per the criteria in 9 CFR
	113.330(c).
	Birds with grossly observable lesions:
	Group 1: 6/30
	Group 2: 27/29
	Group 3: 0/30
	Requirements of 9 CFR 113.330(c) were met.
	Raw data on attached page
USDA Approval Date	May 13, 2021

Group	Animal	Eyes	Skin	Breast Muscle	Heart	Liver	Proventriculus	Spleen	Gonads	Kidney	Intestines	Pancreas	Nerves	Thymus
1	207													
1	209													
1	212													
1	224													
1	243								X					
1	251			X		X		X	X					
1	273			X		X				X			X	X
1	290													
1	296													
1	301													

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				T		I	ı					1	I	1
Group	Animal	Eyes	Skin	Breast Muscle	Heart	Liver	Proventriculus	Spleen	Gonads	Kidney	Intestines	Pancreas	Nerves	Thymus
1	303													
1	312													
1	318													
1	326				X	X		X	X	X	X			
1	329													
1	342													
1	345													
1	356							X	X	X	X			
1	362													
1	364													
1	366													
1	371													
1	378													
1	389													
1	390													
1	391				X	X		X	X	X				
1	397													
1	402													
1	415													
1	416													
2	206				X			X			X			
2	213					X				X	X			
2	214				X	X				X	X			
2	218				X	X								
2	219							X		X	X			
2	234				X			X			X			
2	242	X	X		X	X		X	X		X	X		X
2	279				X			X			X			
2	282												X	
2	286		X		X	X				X				
2	294				X	X			X		X			
2	298				X			X						
2	302				X	X			X		X			
2	306		X			X		X		X				
2	324													

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Group	Animal	Eyes	Skin	Breast Muscle	Heart	Liver	Proventriculus	Spleen	Gonads	Kidney	Intestines	Pancreas	Nerves	Thymus
Ğ	An		<u>S</u>	Breast	He	Li	Proven	Sp	<u>G</u>	Kić	Inte	Pan	Ne	Thy
2	327				X	X				X				
2	337					X				X	X			
2	346					X		X		X	X			
2	355				X	X	X	X		X	X	X		
2	368				X	X		X			X			
2	374	X			X	X	X	X				X		
2	377		X		X	X			X					
2	383				X	X	X	X						
2	384		X		X	X					X			
2	386												X	
2	393					X		X						
2	403													
2	404		X			X		X						
2	407					X		X		X				
3	215													
3	222													
3	227													
3	229													
3	236													
3	239													
3	246													
3	252													
3	253													
3	254													
3	255													
3	258													
3	264													
3	266													
3	275													
3	297													
3	316													
3	320													
3	321													
3	331													
3	332													

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Group	Animal	Eyes	Skin	Breast Muscle	Heart	Liver	Proventriculus	Spleen	Gonads	Kidney	Intestines	Pancreas	Nerves	Thymus
3	335													
3	336													
3	339													
3	357													
3	370													
3	373													
3	382													
3	401				-	-								
3	406													

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Study Type	Efficacy
Pertaining to	Marek's Disease Virus Serotype 3
Study Purpose	Demonstrate efficacy against Marek's Disease
<b>Product Administration</b>	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 sham vaccinated non-challenged (negative control)
<b>Challenge Description</b>	Marek's Disease Virus GA 22 strain given at 5 days of age.
Interval observed after	The birds were observed daily for 49 days, then evaluated for
challenge	grossly observable lesions consistent with Marek's disease
Results	Vaccines and controls were evaluated in terms of Marek's
	disease grossly observable lesions per the criteria in 9 CFR
	113.330(c).
	Birds with grossly observable lesions:
	Group 1: 5/30
	Group 2: 25/30
	Group 3: 0/30
	Requirements of 9 CFR 113.330(c) were met.
	Raw data on attached page
LICDA Approval Data	11 May 2020
USDA Approval Date	11 May 2020

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			L 0				S		es	70
Group	Animal	Skin	Breast Muscle	Heart	Liver	Spleen	Gonads	Kidney	Intestines	Nerves
3	Ar	<b>9</b> 2	B	Ξ	T	S	Ğ	K	Inte	Ž
1	404									
1	408									
1	410									
1	411									
1	416									
1	425									
1	428									
1	430									
1	434									
1	441					X				
1	445									
1	447				X	X		X	X	
1	456									
1	459		X		X			X		
1	461									
1	462									
1	470									
1	475				X				X	
1	476									
1	483									
1	496									
1	509									
1	518									
1	524									
1	532		X		X		X	X		
1	544									
1	545									
1	549									
1	550									
1	560									
2	402		X	X	X		X	X		
2	403			X	X	X	X	X		
2	415			X			X	X	X	
2	421						X	X		
2	427	X			X	X		X	X	
2	429	X		X	X	X		X		
2	433	X		X	X			X	X	

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									×	
Group	Animal	Skin	Breast Muscle	Heart	Liver	Spleen	Gonads	Kidney	Intestines	Nerves
2	435			X	X		X	X		X
2	443	X		X	X	X				
2	453	X		X	X					
2	468			X		X	X	X		
2	472									
2	474			X			X	X		
2	477				X	X		X X		X
2	484									
2	499			X	X	X				
2	502				X				X	
2	503					X		X	X	
2 2	506			X		X				
2	516					X		X	X	
2	517			X	X	X				X
2	523			X				X		
2	527									
2	529				X	X				X
2 2	531	X		X	X	X		X		
2	535	X		X		X		X		
2	543				X	X		X		
2	546			X		X		X		
2	548									
2	556									
3	406									
3	412									
3	414									
3	422									
3	431									
3	436									
3	437									
3	438									
3	442									
3	444									
3	446									
3	451									
3	455									
3	458									

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Group	Animal	Skin	Breast Muscle	Heart	Liver	Spleen	Gonads	Kidney	Intestines	Nerves
			, ,					, ,	<u> </u>	
3	464									
3	465									
3	473									
3	478									
3	481									
3	487									
3	488									
3	494									
3	501									
3	508									
3	537									
3	538									
3	541									
3	553									
3	554									
3	559									

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Study Type	Efficacy
Pertaining to	Newcastle disease Virus (NDV)
Study Purpose	Demonstrate efficacy against Newcastle disease
<b>Product Administration</b>	One dose by <i>in ovo</i> 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	Newcastle Disease Virus strain Texas GB given at 28 days of
	age.
Interval observed after	Birds were daily observed for 14 days post challenge for clinical
challenge	signs of NDV, including mortality.
Results	Vaccines and controls were evaluated in terms of Newcastle
	disease clinical signs per the criteria in 9 CFR 113.329(c).
	Birds with clinical signs, including mortality:
	Group 1: 2/40
	Group 2: 40/40
	Group 3: 0/40
	Requirements of 9 CFR 113.329(c) were met.
	Raw data on attached page
USDA Approval Date	27 April 2020
USDA Appiovai Date	27 11pm 2020

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Group Animal		Clinical Signs of NDV						
I			Respiratory	Mortality				
1	101	· ·	•	•				
1	105							
1	116							
1	117							
1	120							
1	121							
1	129							
1	131							
1	132							
1	133							
1	138	X	X					
1	140							
1	143							
1	164	X	X					
1	173							
1	178							
1	182							
1	186							
1	189							
1	191							
1	196							
1	197							
1	198							
1	201							
1	204							
1	206							
1	213							
1	216							
1	220							
1	221							
1	232							
1	234							
1	239							
1	248							
1	253							
1	254							
1	255							
1	262							
1	270							
1	292							
2	114	X	X					

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		37	137	1
2	122	X	X	
2	125			X
2	136	X	X	
2	147	X	X	
2	148			X
2	149	X	X	
2	150	X	X	
2	161	X X X	X	
2	166	X	X	
2	167	X	X	
2	176			X
2	179	X	X	
2	181	X X	X	
2	183	X	X	
2	187	X	X	
2	193	X X	X	
2	199	X	X	
2	200	X X X X	X	
2	217	X	X	
2	225	X	X X	
2	226	X	X	
2	227	X X	X	
2	231	X	X	
2	236			X
2	242	X	X	
2	243	X	X	
2	245	X	X	
2	246	X	X	
2	251			X
2	252	X	X	
2	258	X	X	
2	259	X	X	
2	260	X	X	
2	279	X	X	
2	280	X	X	
2	287	X	X	
2	288	X	X	
2	289	X	X	
2	291	X	X	
3	102		_	
	103			
3	104			
3	115			
3	123			
3	124			
	144	1		1

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3	145		
3	151		
3	157		
3 3 3	158		
3	159		
	162		
3	163		
3	168		
3	169		
3	170		
3 3 3 3	172		
3	180		
3	184		
3 3 3 3	185		
3	194		
3	202		
3	211		
3	212		
3	214		
3	222		
3 3 3 3	223		
3	228		
3	229		
3	240		
3	250		
3	256		
3 3 3	257		
3	268		
	269		
3	277		
3	278		
3	281		
3 3 3	284		
3	290		

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Study Type	Efficacy
Pertaining to	Newcastle Disease Virus (NDV)
Study Purpose	Demonstrate effectiveness against NDV 63 days after
_	vaccination
<b>Product Administration</b>	One dose by the <i>in ovo</i> route
Study Animals	Chicken eggs at 18 days of embryonation, divided into 3 groups:
	Group 1 vaccinated with product in ovo and challenged
	Group 2 placebo vaccinated and challenged (control)
	Group 3 placebo vaccinated and not challenged (control)
<b>Challenge Description</b>	NDV Texas GB strain given at 63 days after vaccination
Interval observed after	The birds were observed daily for 14 days post-challenge
challenge	
Results	Vaccines 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: 0/28 Group 2: 29/29 Group 3: 0/30  Requirements of 9 CFR 113.329(c)(4) were met.  Raw data on attached page
USDA Approval Date	September 21, 2020

		Clinical Signs of NDV				
Group	Bird	Mortality	Depression	Paralysis	Respiratory	
1	110					
1	111					
1	129					
1	132					
1	137					
1	169					
1	180					
1	186					
1	189					
1	192					
1	214					

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1       218         1       230         1       235         1       247         1       248         1       250         1       264         1       271         1       272         1       274         1       296         1       298         1       300         1       307         1       322         1       325         1       339         2       113         X       X         2       143         2       143         2       148         2       150         2       152         2       153         2       153         2       157         2       157         2       166         2       172         2       182         2       190         X       X         2       191         X       X         2       191         X       X <tr< th=""><th></th><th></th><th></th><th></th><th></th></tr<>					
1       235         1       247         1       248         1       250         1       264         1       271         1       272         1       296         1       298         1       300         1       307         1       322         1       339         2       113         X       X         2       143         2       148         X       X         2       150         X       X         2       153         2       155         X       X         2       157         X       X         2       172         X       X         2       190         X       X         2       195         X       X         2       222         X       X         2       225         X       X	1	218			
1       247         1       248         1       250         1       264         1       271         1       272         1       274         1       298         1       300         1       307         1       322         1       325         1       339         2       113         X       X         2       143         2       148         2       150         2       152         2       153         2       155         2       157         2       166         2       172         2       182         2       190         X       X         2       195         X       X         2       201         X       X         2       225         X       X	1	230			
1       248         1       250         1       264         1       271         1       272         1       274         1       296         1       298         1       300         1       307         1       322         1       325         1       339         2       113         2       143         2       148         2       150         2       152         2       153         2       155         2       157         2       157         2       172         2       182         2       190         2       201         X       X         2       201         X       X         2       222         X       X         2       225         X       X	1	235			
1       250         1       264         1       271         1       272         1       296         1       298         1       300         1       307         1       322         1       339         2       113         2       143         2       148         2       150         2       152         2       153         2       153         2       155         2       157         2       157         2       172         2       182         2       190         2       191         2       201         X       X         2       201         X       X         2       217         2       222         2       225         X       X	1	247			
1       264         1       271         1       272         1       274         1       296         1       298         1       300         1       307         1       322         1       339         2       113         2       139         2       143         2       148         2       150         2       152         2       153         2       153         2       155         2       157         2       157         2       172         2       182         2       190         2       191         2       195         2       201         X       X         2       217         2       225         X       X	1	248			
1       271         1       272         1       274         1       296         1       300         1       307         1       322         1       339         2       113         2       139         2       143         2       148         2       150         2       152         2       153         2       155         2       155         2       157         2       157         2       172         2       182         2       190         2       191         2       195         2       201         X       X         2       217         2       225         X       X	1	250			
1       272         1       274         1       296         1       298         1       300         1       307         1       322         1       325         1       339         2       113         2       143         2       148         2       150         2       152         2       153         2       153         2       155         2       157         2       157         2       166         2       172         2       182         2       190         2       191         X       X         2       195         2       201         X       X         2       217         X       X         2       225         X       X	1	264			
1       274         1       296         1       298         1       300         1       307         1       322         1       325         1       339         2       113         2       143         2       148         2       150         2       152         2       152         2       153         2       155         2       157         2       157         2       166         2       172         2       182         2       190         3       3         2       191         3       3         3       4         4       4         5       4         6       4         7       4         8       4         9       4         1       4         1       4         1       4         2       4         3       4         4	1	271			
1       296         1       298         1       300         1       307         1       322         1       325         1       339         2       113         2       139         2       143         2       148         2       150         2       152         2       153         2       153         2       155         2       157         2       166         2       172         2       182         2       190         X       X         2       191         X       X         2       195         X       X         2       201         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X	1	272			
1       298         1       300         1       307         1       322         1       325         1       339         2       113         2       139         2       143         2       148         2       150         2       152         2       153         2       153         2       155         2       157         2       157         2       166         2       172         2       182         2       190         2       191         2       195         2       201         X       X         2       217         2       222         X       X	1	274			
1       300         1       307         1       322         1       325         1       339         2       113         2       139         2       143         2       148         2       150         2       152         2       153         2       155         2       157         2       157         2       166         2       172         2       182         2       190         2       191         2       195         2       201         X       X         2       201         X       X         2       217         2       222         X       X	1	296			
1       307         1       322         1       325         1       339         2       113         2       143         2       148         2       150         2       152         2       153         2       155         2       157         2       166         2       172         2       182         2       190         X       X         2       195         X       X         2       195         X       X         2       201         X       X         2       222         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       <	1	298			
1       322         1       325         1       339         2       113         2       139         2       143         2       148         2       150         2       152         2       153         2       155         2       157         2       166         2       172         2       182         2       190         2       191         2       195         2       201         X       X         2       217         2       222         X       X	1	300			
1       325         1       339         2       113         2       139         2       143         2       148         2       150         2       152         2       153         2       155         2       157         2       157         2       166         2       172         2       182         2       190         2       191         2       195         2       201         X       X         2       217         2       222         X       X	1	307			
1       339         2       113       X         2       143       X         2       148       X       X         2       150       X       X         2       152       X       X         2       153       X       X         2       155       X       X         2       157       X       X         2       172       X       X         2       172       X       X         2       190       X       X       X         2       191       X       X       X         2       195       X       X       X         2       201       X       X       X       X         2       227       X       X       X       X         2       225       X       X       X       X	1	322			
2       113       X         2       139       X         2       143       X         2       148       X       X         2       150       X       X         2       152       X       X         2       153       X       X         2       155       X       X         2       157       X       X         2       166       X       X         2       172       X       X         2       190       X       X       X         2       191       X       X       X         2       195       X       X       X         2       201       X       X       X         2       217       X       X       X         2       225       X       X       X	1	325			
2       113       X         2       139       X         2       143       X         2       148       X       X         2       150       X       X         2       152       X       X         2       153       X       X         2       155       X       X         2       157       X       X         2       166       X       X         2       172       X       X         2       190       X       X       X         2       191       X       X         2       195       X       X         2       201       X       X         2       227       X       X         2       225       X       X	1	339			
2       143       X       X         2       148       X       X         2       150       X       X         2       152       X       X         2       153       X       X         2       157       X       X         2       166       X       X         2       172       X       X         2       182       X       X         2       190       X       X       X         2       191       X       X       X         2       195       X       X       X         2       201       X       X       X         2       227       X       X       X         2       225       X       X       X	2		X		
2       148       X       X         2       150       X       X         2       152       X       X         2       153       X       X         2       155       X       X         2       166       X       X         2       172       X       X         2       182       X       X         2       190       X       X       X         2       191       X       X       X         2       201       X       X       X         2       217       X       X       X         2       222       X       X       X         2       225       X       X       X	2	139		X	
2       150       X         2       152       X       X         2       153       X       X         2       155       X       X         2       166       X       X         2       172       X       X         2       182       X       X         2       190       X       X       X         2       191       X       X       X         2       201       X       X       X         2       217       X       X       X         2       222       X       X       X         2       225       X       X       X	2	143			X
2       152       X       X         2       153       X       X         2       155       X       X         2       157       X       X         2       166       X       X         2       182       X       X         2       190       X       X       X         2       191       X       X       X         2       201       X       X       X         2       217       X       X       X         2       222       X       X       X         2       225       X       X       X	2	148		X	X
2       153       X         2       155       X         2       157       X       X         2       166       X         2       172       X         2       182       X         2       190       X       X         2       191       X       X         2       195       X       X         2       201       X       X         2       217       X       X         2       222       X       X         2       225       X       X	2	150		X	
2       155       X       X         2       157       X       X         2       166       X       X         2       172       X       X         2       182       X       X         2       190       X       X         2       191       X       X         2       195       X       X         2       201       X       X         2       217       X       X         2       222       X       X         2       225       X       X	2	152		X	X
2       157       X       X         2       166       X         2       172       X         2       182       X         2       190       X       X         2       191       X       X         2       195       X       X         2       201       X       X         2       217       X       X         2       222       X       X         2       225       X       X	2	153			X
2     166       2     172       2     182       2     190       2     191       2     195       2     201       2     217       2     222       2     225	2	155		X	
2     172     X       2     182     X       2     190     X     X       2     191     X     X       2     195     X       2     201     X       2     217     X       2     222     X       2     225     X	2	157		X	X
2       182       X         2       190       X       X         2       191       X       X         2       195       X       X         2       201       X       X         2       217       X       X         2       222       X       X         2       225       X       X	2	166		X	
2     190     X     X       2     191     X     X       2     195     X       2     201     X       2     217     X       2     222     X       2     225     X	2	172		X	
2       191       X       X         2       195       X         2       201       X         2       217       X         2       222       X         2       225       X	2	182		X	
2     195     X       2     201     X       2     217     X       2     222     X       2     225     X	2	190		X	X
2     201     X       2     217     X       2     222     X       2     225     X	2	191			X
2     217     X       2     222     X       2     225     X		195		X	
2 222 X 2 225 X	2	201	X		
2 225 X	2	217		X	
	2	222	X		
2 228 X X	2	225			
	2	228		X	X

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2	234			X
2	260		X	X
2	263		X	
2	266		X	X
2	269		X	
2	270		X	X
2	275		X	X
2	281			X
2	312		X	X
3	106			
3	117			
3	121			
3	133			
3	136			
3	140			
3	141			
3	149			
3	151			
3	154			
3	156			
3	163			
3	175			
3	176			
3	188			
3	194			
3	200			
3	202			
3	208			
3	243			
3	255			
3	291			
3	297			
3	302			
3	305			
3	313			
3	321			
3	327			

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3	330		
3	331		

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Study Type	Efficacy
Pertaining to	Newcastle Disease Virus (NDV)
Study Purpose	Demonstrate effectiveness against NDV 63 days after
	vaccination
<b>Product Administration</b>	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 (control)
	Group 3 placebo vaccinated not challenged (control)
Challenge Description	NDV Texas GB strain given at 63 days after vaccination
Interval observed after	The birds were observed daily for 14 days post-challenge
challenge	, , , , ,
Results	Vaccines 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: 1/30
	Group 2: 29/29
	Group 3: 0/30
	Requirements of 9 CFR 113.329(c)(4) were met.
	Raw data on attached page
<b>USDA Approval Date</b>	September 21, 2020

		Clinical Signs of NDV						
Group	Bird	Mortality	Depression	Paralysis	Respiratory			
1	101							
1	112							
1	116							
1	123							
1	124							
1	128							
1	145							
1	158							
1	160							
1	167							
1	170							

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1       197         1       207       X         1       211         1       221         1       221         1       237         1       244         1       254         1       276         1       284         1       286         1       292         1       314         1       323         1       332         1       334         1       336         2       113         X       X         2       143         2       143         2       143         2       148         2       150         2       152         2       153         2       155         2       157         2       166         2       172         2       182         2       190         X       X         2       191         X       X         2       195         X       X	1	170		<u> </u>	T	T
1       207       X         1       211         1       221         1       237         1       241         1       254         1       276         1       284         1       286         1       292         1       314         1       323         1       332         1       334         1       336         2       113         X       X         2       143         2       148         2       150         2       152         X       X         2       157         X       X         2       157         X       X         2       166         X       X         2       190         X       X         2       195         X       X         2       201         X       X	1	178				
1       211         1       221         1       237         1       241         1       254         1       276         1       284         1       286         1       292         1       314         1       323         1       332         1       334         1       336         2       113         X       X         2       143         2       148         2       150         2       152         2       153         2       157         2       157         2       172         2       182         2       190         X       X         2       195         2       201         X       X						
1       221         1       237         1       241         1       254         1       276         1       284         1       286         1       292         1       314         1       323         1       329         1       332         1       334         1       336         2       113         2       139         2       143         2       148         2       150         2       152         2       153         2       157         2       157         2       166         2       172         2       182         2       190         X       X         2       195         X       X         2       201         X       X         2       217			X			
1       237         1       241         1       254         1       276         1       284         1       286         1       292         1       314         1       323         1       332         1       334         1       336         2       113         2       139         2       143         2       148         2       150         2       152         2       153         2       157         2       157         2       166         2       172         2       182         2       190         2       191         X       X         2       195         2       201         X       X						
1       241         1       254         1       273         1       276         1       284         1       286         1       292         1       314         1       323         1       332         1       334         1       336         2       113         2       143         2       143         2       148         2       150         2       152         2       153         2       157         2       157         2       166         2       172         2       182         2       190         2       191         X       X         2       195         X       X         2       195         2       201         X       X						
1       254         1       273         1       276         1       284         1       286         1       292         1       314         1       323         1       332         1       334         1       336         2       113         2       139         2       143         2       148         2       150         2       152         2       153         2       157         2       157         2       157         2       166         2       172         2       182         2       190         2       191         X       X         2       195         X       X         2       195         2       201         X       X						
1       273         1       276         1       284         1       292         1       314         1       323         1       329         1       332         1       336         2       113         2       143         2       148         2       150         2       152         2       153         2       155         2       157         2       157         2       152         2       153         2       152         2       153         2       157         2       152         2       153         2       157         2       152         2       157         2       159         2       190         2       201         X       X         2       201         X       X	1	241				
1       276         1       284         1       286         1       292         1       314         1       323         1       332         1       334         1       336         2       113         2       143         2       148         2       150         2       152         2       153         2       155         2       157         2       157         2       166         2       172         2       182         2       190         2       191         X       X         2       195         2       201         X       X	1	254				
1       284         1       286         1       292         1       314         1       323         1       332         1       334         1       336         2       113         2       143         2       148         2       150         2       152         2       153         2       155         2       157         2       157         2       166         2       172         2       182         2       190         2       191         X       X         2       195         X       X         2       201         X       X	1	273				
1       292         1       314         1       323         1       329         1       332         1       334         1       336         2       113         2       143         2       148         2       150         2       152         2       153         2       155         2       157         2       166         2       172         2       182         2       191         2       195         2       191         X       X         2       191         X       X         2       195         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X	1	276				
1       292         1       314         1       323         1       329         1       332         1       334         1       336         2       113         2       139         2       143         2       148         2       150         2       152         2       153         2       155         2       155         2       157         2       166         2       172         2       182         2       190         X       X         2       191         X       X         2       195         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X	1	284				
1       314         1       323         1       329         1       334         1       336         2       113         2       139         2       143         2       148         2       150         2       152         2       153         2       155         2       157         2       166         2       172         2       182         2       190         2       191         X       X         2       195         2       201         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X	1	286				
1       323         1       329         1       332         1       334         1       336         2       113         2       139         2       143         2       148         2       150         2       152         2       153         2       155         2       157         2       157         2       157         2       166         2       172         2       182         2       190         2       191         X       X         2       195         2       201         X       X	1	292				
1       329         1       332         1       334         1       336         2       113         2       139         2       143         2       148         2       150         2       152         2       153         2       155         2       157         2       166         2       172         2       182         2       190         X       X         2       191         X       X         2       195         X       X         2       201         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       X         X       <	1	314				
1       334         1       336         2       113         2       139         2       143         2       148         2       150         2       152         2       153         2       155         2       157         2       157         2       166         2       172         2       182         2       190         2       191         2       201         2       201         2       201         2       201         2       201         2       201         2       201         2       201         2       201         2       201         2       201         2       217	1	323				
1       334         1       336         2       113       X         2       143       X         2       148       X       X         2       150       X       X         2       152       X       X         2       153       X       X         2       155       X       X         2       157       X       X         2       166       X       X         2       172       X       X         2       190       X       X         2       191       X       X         2       195       X       X         2       201       X       X         2       217       X       X	1	329				
1       336         2       113       X         2       139       X         2       143       X         2       148       X       X         2       150       X       X         2       152       X       X         2       153       X       X         2       155       X       X         2       157       X       X         2       166       X       X         2       172       X       X         2       182       X       X         2       190       X       X       X         2       191       X       X       X         2       201       X       X       X         2       201       X       X       X	1	332				
2       113       X         2       139       X         2       143       X         2       148       X         2       150       X         2       152       X         2       153       X         2       155       X         2       157       X         2       166       X         2       172       X         2       182       X         2       190       X       X         2       191       X       X         2       195       X       X         2       201       X       X	1	334				
2       139       X         2       143       X         2       148       X         2       150       X         2       152       X         2       153       X         2       155       X         2       157       X       X         2       166       X         2       172       X         2       182       X         2       190       X       X         2       191       X       X         2       195       X       X         2       201       X       X         2       217       X       X	1	336				
2       143       X       X         2       148       X       X         2       150       X       X         2       152       X       X         2       153       X       X         2       155       X       X         2       157       X       X         2       166       X       X         2       172       X       X         2       190       X       X         2       191       X       X         2       195       X       X         2       201       X       X         2       217       X       X	2	113	X			
2       148       X       X         2       150       X       X         2       152       X       X         2       153       X       X         2       155       X       X         2       157       X       X         2       166       X       X         2       172       X       X         2       182       X       X         2       190       X       X         2       191       X       X         2       195       X       X         2       201       X       X	2	139			X	
2     150       2     152       2     153       2     155       2     157       2     166       2     172       2     182       2     190       2     191       2     195       2     217       2     217	2	143				X
2       152       X       X         2       153       X       X         2       155       X       X         2       157       X       X         2       166       X       X         2       172       X       X         2       182       X       X         2       190       X       X         2       191       X       X         2       201       X       X         2       217       X       X	2	148			X	X
2       153       X         2       155       X         2       157       X         2       166       X         2       172       X         2       182       X         2       190       X       X         2       191       X       X         2       195       X       X         2       201       X       X         2       217       X       X	2	150			X	
2     155     X       2     157     X     X       2     166     X       2     172     X       2     182     X       2     190     X     X       2     191     X     X       2     195     X       2     201     X       2     217     X	2	152			X	X
2       157       X       X         2       166       X         2       172       X         2       182       X         2       190       X       X         2       191       X       X         2       195       X       X         2       201       X       X         2       217       X       X	2	153				X
2       166       X         2       172       X         2       182       X         2       190       X       X         2       191       X       X         2       195       X       X         2       201       X       X         2       217       X       X	2	155			X	
2     172     X       2     182     X       2     190     X     X       2     191     X     X       2     195     X       2     201     X       2     217     X	2	157			X	X
2       182       X         2       190       X       X         2       191       X       X         2       195       X       X         2       201       X       X         2       217       X       X	2	166			X	
2       190       X       X         2       191       X       X         2       195       X         2       201       X         2       217       X	2	172			X	
2       191       X       X         2       195       X         2       201       X         2       217       X	2	182			X	
2       191       X       X         2       195       X         2       201       X         2       217       X	2	190			X	X
2 201 X 2 217 X		191			X	X
2 201 X 2 217 X	2	195			X	
		201	X			
	2	217			X	
	2		X			

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2	225	X	
2	228	X	X
2	234		X
2	260	X	X
2	263	X	
2	266	X	X
2	269	X	
2	270	X	X
2	275	X	X
2	281		X
2	312	X	X
3	106		
3	117		
3	121		
3	133		
3	136		
3	140		
3	141		
3	149		
3	151		
3	154		
3	156		
3	163		
3	175		
3	176		
3	188		
3	194		
3	200		
3	202		
3	208		
3	243		
3	255		
3	291		
3	297		
3	302		
3	305		
3	313		

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3	321		
3	327		
3	330		
3	331		

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Study Type	Efficacy							
Pertaining to	Newcastle disease Virus							
<b>Study Purpose</b>	Demonstrate efficacy against Newcastle disease							
<b>Product Administration</b>	One dose by 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 Newcastle Disease Virus strain Texas GB given at 28							
	days of age.							
Interval observed after	Birds were daily observed for 14 days post challenge.							
challenge								
Results	Vaccines and controls were evaluated in terms of Newcastle							
	disease clinical signs per the criteria in 9 CFR 113.329(c).							
	Birds with clinical signs, including mortality:							
	Group 1: 0/40							
	Group 2: 40/40							
	Group 3: 1/40							
	Requirements of 9 CFR 113.329(c) were met.							
	Raw data on attached page							
USDA Annroval Date	April 28, 2020							
USDA Approval Date	April 28, 2020							

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

Group	Animal	Clinical Si	igns of NDV		
		Paralysis	Depression	Respiratory	Mortality
1	308				
1	313				
1	322				
1	325				
1	330				
1	331				
1	332				
1	338				
1	346				
1	351				
1	353				
1	354				
1	358				

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		1	1	1	1
1	362				
1	373				
1	375				
1	377				
1	382				
1	383				
1	385				
1	390				
1	400				
1	401				
1	406				
1	407				
1	415				
1	420				
1	428				
1	432				
1	447				
1	452				
1	456				
1	461				
1	468				
1	469				
1	470				
1	475				
1	480				
1	483				
1	490				
2	301	X	X	X	
2	305	X	X	X	
2.	312	X	X	X	
2 2	314	X	X	X	
2	315	X	X	X	
2	316	X	X	X	
2	319	X	X	X	
2	329	X	X	X	
2	333	X	X	X	
2	334	X	X	X	
2	342	X	X	X	
2	344	X	X	X	
2	356	X	X	X	
2	360	X	X	X	
2	364	X	X	X	
2	368	X	X	X	
2	379	X	X	X	
2	380	X	X	X	
	1 2 3 0	1		1	<u>I</u>

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2	204	37	37	37	
2	384	X	X	X	
2 2 2 2	387	X	X	X	37
2	395				X
2	398				X
2	404	X	X	X	
2	405	X	X	X	
2	408				X
2	409	X	X	X	
2	412				X
2	416	X	X	X	
2	417	X	X	X	
2	421				X
2	424	X	X	X	
2	425	X	X	X	
2	426	X	X	X	
2 2 2 2 2 2 2 2 2 2	434	X X X	X X	X X X	
2	464	X	X	X	
2	467				X
2	472	X	X	X	
2	481				X
2	485	X	X	X	
2	491	X	X	X	
3	304				
3	307				
3	309				
3	320				
3	321				
3	337				
3	341				
3	352				
3 3 3 3 3 3 3 3	355				
3	357				
3	366				
3	369				
3	371				
3	376				
3	388				
3	389				
3	396				
3	397				
3	402				
3	411				
3	422				
3	433				
3	437				
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3	443		
3	444		
3	446		
3	448		
3	454		
3	455		
3	457		
3	460		
3	463		X
3	473		
3	477		
3	478		
3	479		
3	482		
3	484		
3	486		

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Study Type	Safety						
Pertaining to	ALL	ALL					
Study Purpose	To demons	trate	safety	under field	condition	ons.	
Product	One dose a	dmin	istered	in ovo (IO	) or sub	cutaneously (	SC) at day-
Administration	of-hatch.						
Study Animals	Approxima	ately	237,45	2 commerci	ial broil	er chickens	
-	Site A: Va	ccina	tes: 34	300, Contro	ols: 34,3	300	
	Site B: Vac	ecina	tes: 26,	900, Contro	ols: 26,9	900	
	Site C: Vac	ccina	tes: 58,	058, Contro	ols: 56,9	94	
<b>Challenge Description</b>							
Interval observed							
after challenge							
Results							
						Overall Mortality (%)	Total Condemnation
				Percent	Total	35 to 62 days-	Rates (%)
	Description	Site	Route	Hatchability	Placed	of-age	, ,
		A	IO	87.30	34,300	5.64	0.167
	Vaccinates	В	IO	86.13	26,900	4.09	0.130
		С	SC	NA	58,058	5.16	0.716
		A	Ю	83.55	34,300	5.08	0.672
	Controls	В	IO	79.07	26,900	3.30	0.168
		С	SC	NA	56,994	5.87	0.791
USDA Approval Date	September	13, 2	2021				
Coll rippio in Date	~ *P************	, -					

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