



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
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)	Innofusion-ND - Intervet Columbia Ltda Innovax ND - Merck Animal Health Innovax ND - No distributor specified Merck Animal Health Merck Sharpe and Dohme (MSD)
Date of Compilation Summary	October 25, 2021

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	ALL
Study Purpose	To demonstrate effectiveness against disease caused by Marek's Disease Virus (MDV) and Newcastle Disease Virus (NDV)
Product Administration	<i>In ovo</i>
Study Animals	Chickens
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	March 11, 2004

Study Type	Efficacy
Pertaining to	Marek's Disease Virus (MDV)
Study Purpose	To demonstrate effectiveness against disease caused by Marek's Disease Virus
Product Administration	One dose administered <i>in ovo</i> at 18 days of embryonation.
Study Animals	Group 2: 35 embryos, vaccine treatment Group 3A: 35 Challenged Placebo controls Group 4: 25 Non-challenged Placebo controls
Challenge Description	Challenged with MDV, GA5 strain challenge virus at 5 days of age.
Interval observed after challenge	Observed for clinical signs through 49 days of age. All birds were necropsied at the end of the observation period.
Results	<p>Summary of results:</p> <p>Birds positive for Marek's Disease:</p> <p>Vaccinates (Group 2): 3/34*</p> <p>Positive Controls (Group 3A): 32/34</p> <p>Negative Controls (Group 4): 0/24</p> <p>*One chicken died from causes unrelated to challenge and was not included in the analysis.</p> <p>Requirements per 9 CFR 113.330(c) were met.</p> <p>Raw data attached</p>
USDA Approval Date	May 20, 2010

**Individual Bird Necropsy Data
Gross Lesions Associated with MDV
Vaccinates (Group 2)**

Bird ID#	Paralysis	Heart	Liver	Spleen	Gonads	Kidneys	Proven	Nerves	Skin	Comments	Result (+ or -)
680	-	-	-	-	-	-	-	-	-		-
698	-	-	-	-	-	-	-	-	-		-
705	-	-	-	-	-	-	-	-	-		-
721	-	-	-	-	-	-	-	-	-		-
729	-	-	-	-	-	-	-	-	-		-
733	-	-	-	-	-	-	-	-	-		-
683	-	-	-	-	-	-	-	-	-		-
686	-	-	-	-	-	-	-	-	-		-
700	-	-	-	-	-	-	-	-	-		-
712	-	-	-	-	-	-	-	-	-		-
718	-	-	-	-	-	-	-	-	-		-
735	-	-	-	-	-	-	-	-	-		-
674	-	-	-	-	-	-	-	-	-		-
681	-	-	-	-	-	-	-	-	-		-
690	-	+	-	+	-	+	-	-	-	Breast tumor	+
693	-	-	-	-	-	-	-	-	-		-
709	-	-	-	-	-	-	-	-	-		-
724	-	-	-	-	-	-	-	-	-		-
670	-	-	-	-	-	-	-	-	-		-
682	-	-	-	-	-	-	-	-	-		-
697	-	-	-	-	-	-	-	-	-		-
727	-	-	-	-	-	-	-	-	-		-
732	-	-	-	-	-	-	-	-	-		-
679	-	-	-	-	-	-	-	-	-		-
691	-	-	-	-	-	-	-	-	-		-
703	-	-	-	-	-	-	-	-	-		-
713	-	-	-	-	-	-	-	-	-		-
720	-	-	-	-	-	-	-	-	-		-
726	-	-	-	-	-	-	-	-	-		-
677	-	-	-	-	-	-	-	-	-		-
685	-	-	-	-	-	-	-	-	-		-
694	+	+	-	-	-	+	-	-	-	Emaciated	+
710	-	-	-	-	-	-	-	-	-	Breast tumor	+
734	-	-	-	-	-	-	-	-	-		-

**Individual Bird Necropsy Data
Gross Lesions Associated with MDV
Positive Controls (Group 3A)**

Bird ID#	Paralysis	Heart	Liver	Spleen	Gonads	Kidneys	Proven	Nerves	Skin	Comments	Result (+ or -)
747	-	-	-	-	-	-	-	-	-		-
750	+	+	+	+	-	+	+	-	-	Emaciated	+
756	-	-	+	+	-	+	+	-	-	Emaciated, dehydrated	+
759	-	+	+	-	+	+	+	-	-	Small, tumors on breast	+
764	-	-	+	+	-	+	-	-	-	Small	+
767	-	-	-	-	-	-	+	-	-	Small	+
744	-	+	-	+	-	+	-	-	-	Small	+
752	-	-	-	-	-	-	-	-	-		-
755	-	-	-	+	+	-	-	-	-		+
758	-	+	+	-	-	+	+	-	-	Emaciated	+
766	-	+	+	+	-	-	+	-	-		+
771	-	+	+	+	-	+	-	-	-	Emaciated	+
741	-	-	+	+	-	+	-	-	-	Small, Emaciated	+
745	-	-	+	+	-	+	-	-	-	Small, Emaciated	+
748	-	+	-	+	-	+	-	-	-	Emaciated	+
760	-	-	-	-	-	-	-	-	-	Small	+
761	-	-	-	+	-	+	+	-	-	Breast tumor, emaciated	+
763	-	+	+	+	-	+	-	-	-	Small	+
738	-	+	-	-	-	+	-	-	-	Small, intestinal tumors	+
749	-	+	+	+	-	+	+	-	+	Emaciated, dehydrated	+
753	-	-	-	-	-	-	-	-	-	Small, emaciated	+
754	-	-	-	-	+	+	-	-	-	Small	+
770	-	+	-	+	-	+	-	-	-	Breast tumor, emaciated	+
737	-	-	-	-	-	-	-	-	-	Uncoordinated; emaciated	+
739	+	-	+	+	-	-	+	-	-	Emaciated	+
742	-	+	+	+	-	+	-	-	-	Emaciated	+
751	-	-	-	-	-	-	-	-	-	Small, emaciated	+
768	-	-	-	+	-	-	-	-	-	Small	+
740	+	-	-	-	-	-	-	-	-	Completely paralyzed, Emaciated	+
743	-	+	-	-	-	+	+	-	-	Emaciated	+
746	-	+	-	-	-	+	+	-	-	Emaciated	+
757	+	-	+	+	-	-	+	-	-		+
765	+	-	-	-	-	-	-	-	-	Emaciated, dehydrated	+
769	-	-	+	-	-	-	-	-	-	Small	+

**Individual Bird Necropsy Data (continued)
Gross Lesions Associated with MDV
Negative Controls (Group 4)**

Bird ID#	Paralysis	Heart	Liver	Spleen	Gonads	Kidneys	Proven	Nerves	Skin	Comments	Result (+ or -)
785	-	-	-	-	-	-	-	-	-		-
786	-	-	-	-	-	-	-	-	-		-
787	-	-	-	-	-	-	-	-	-		-
789	-	-	-	-	-	-	-	-	-		-
790	-	-	-	-	-	-	-	-	-		-
791	-	-	-	-	-	-	-	-	-		-
792	-	-	-	-	-	-	-	-	-		-
793	-	-	-	-	-	-	-	-	-		-
796	-	-	-	-	-	-	-	-	-		-
800	-	-	-	-	-	-	-	-	-		-
802	-	-	-	-	-	-	-	-	-		-
806	-	-	-	-	-	-	-	-	-		-
784	-	-	-	-	-	-	-	-	-		-
788	-	-	-	-	-	-	-	-	-		-
794	-	-	-	-	-	-	-	-	-		-
795	-	-	-	-	-	-	-	-	-		-
797	-	-	-	-	-	-	-	-	-		-
798	-	-	-	-	-	-	-	-	-		-
799	-	-	-	-	-	-	-	-	-		-
803	-	-	-	-	-	-	-	-	-		-
804	-	-	-	-	-	-	-	-	-		-
805	-	-	-	-	-	-	-	-	-		-
807	-	-	-	-	-	-	-	-	-		-
808	-	-	-	-	-	-	-	-	-		-

Study Type	Efficacy
Pertaining to	Marek's Disease Virus (MDV) and Newcastle Disease Virus (NDV)
Study Purpose	To demonstrate effectiveness against disease caused by MDV and NDV
Product Administration	One dose administered by the subcutaneous route at 1 day of age.
Study Animals	Group 2A: 35 chickens, MDV vaccine treatment Group 2B: 32 chickens, NDV vaccine treatment Group 3: 35 non-vaccinated MDV positive controls Group 4: 12 non-vaccinated NDV positive controls Group 5: 25 non-vaccinated, non-challenged MDV negative controls
Challenge Description	Groups 2A and 3: Challenged with MDV challenge virus at 5 days of age Groups 2B and 4: Challenged with NDV challenge virus, Texas GB Strain, at 28 days of age
Interval observed after challenge	Observed for clinical signs of MDV through 49 days of age. All birds were necropsied at the end of the observation period. Observed for clinical signs of NDV through 42 days of age.
Results	Summary of results: Birds positive for Marek's Disease: Group 2A Vaccinates: 2/35 Group 3 Positive Controls: 33/34* Group 5 Negative Controls: 0/25 *One chicken died from causes unrelated to challenge and was removed from analysis. Requirements per 9 CFR 113.330(c) were met. Birds positive for Newcastle Disease: Group 2B Vaccinates: 0/32 Group 4 Positive Controls: 12/12 Requirements per 9 CFR 113.329 were met. Raw data attached.
USDA Approval Date	June 16, 2009

**Individual Bird Necropsy Data
Marek's Challenge – Vaccinates (Group 2A)
Gross Lesions Associated with MDV**

Bird ID#	Paralysis	Liver	Heart	Spleen	Prov.	Kidneys	Gonads	Nerves	Skin	Comments	Result (+ or -)
494	-	-	-	-	-	-	-	-	-		-
481	-	-	-	-	-	-	-	-	-		-
490	-	-	-	-	-	-	-	-	-		-
480	-	-	-	-	-	-	-	-	-		-
489	-	-	-	-	-	-	-	-	-		-
393	-	-	-	-	-	-	-	-	-		-
438	-	-	-	-	-	-	-	-	-		-
432	-	-	-	-	-	-	-	-	-		-
308	-	-	-	-	-	-	-	-	-		-
317	-	-	-	-	-	-	-	-	-		-
456	-	-	-	-	-	-	-	-	-		-
445	-	-	-	-	-	-	-	-	-		-
348	-	-	-	-	-	-	-	-	-		-
388	-	-	-	-	-	-	-	-	-		-
431	-	-	-	-	-	-	-	-	-		-
409	-	-	-	-	-	-	-	-	-		-
344	-	-	-	-	-	-	+	-	-		+
371	-	-	-	-	-	-	-	-	-		-
497	-	-	-	-	-	-	-	-	-		-
346	-	-	-	-	-	-	-	-	-		-
394	-	+	-	-	-	-	-	-	-		+
486	-	-	-	-	-	-	-	-	-		-
339	-	-	-	-	-	-	-	-	-		-
362	-	-	-	-	-	-	-	-	-		-
482	-	-	-	-	-	-	-	-	-		-
338	-	-	-	-	-	-	-	-	-		-
387	-	-	-	-	-	-	-	-	-		-
306	-	-	-	-	-	-	-	-	-		-
319	-	-	-	-	-	-	-	-	-		-
440	-	-	-	-	-	-	-	-	-		-
461	-	-	-	-	-	-	-	-	-		-
336	-	-	-	-	-	-	-	-	-		-
361	-	-	-	-	-	-	-	-	-		-
377	-	-	-	-	-	-	-	-	-		-
474	-	-	-	-	-	-	-	-	-		-

**Individual Bird Necropsy Data
Marek's Challenge – Positive Controls (Group 3)
Gross Lesions Associated with MDV**

Bird ID#	Paralysis	Liver	Heart	Spleen	Proven.	Kidneys	Gonads	Nerves	Skin	Comments	Result (+ or -)
465	-	+	+	+	-	+	-	-	-	Emaciated	+
478	-	+	+	+	+	+	-	-	-	Intestinal tumors, emaciated	+
416	+	+	+	+	+	-	-	-	-	Emaciated	+
316	-	-	-	+	-	+	-	-	-	Emaciated	+
303	-	-	-	-	-	-	-	-	-		-
452	-	+	+	+	+	-	-	-	-		+
367	-	+	-	+	+	+	-	-	-		+
429	-	+	+	+	+	+	-	-	-	Emaciated, intestinal tumors	+
419	+	+	-	+	-	+	-	-	-	Emaciated	+
380	+	+	+	+	+	+	-	-	-	Emaciated	+
451	-	+	+	+	-	-	-	-	+		+
384	-	+	+	-	-	-	-	-	+		+
450	-	-	-	-	-	-	-	-	-	Severely pecked, injured legs	N/A
323	-	+	+	-	-	-	-	-	-		+
164	-	+	+	+	-	+	+	-	-		+
473	-	-	-	+	-	+	-	-	-		+
310	-	+	-	+	+	+	+	-	-		+
369	+	+	+	+	+	-	-	-	-		+
313	-	+	-	+	+	-	-	-	-	Emaciated	+
491	-	+	+	+	-	-	-	-	-		+
420	-	+	-	+	-	-	-	-	-		+
422	-	+	+	+	+	+	-	-	-		+
441	-	+	-	+	+	-	-	-	-	Tumor in intestines, Emaciated	+
408	-	+	+	+	+	-	-	-	-	Emaciated	+
368	-	+	-	+	-	+	-	-	-		+
423	-	+	+	+	-	+	-	-	-	Emaciated	+
366	-	+	+	+	+	+	-	-	-	Emaciated, dehydrated	+
381	-	-	-	+	-	+	-	-	-	Emaciated	+
448	+	+	-	+	+	+	+	-	-	Emaciated, tumors in intestines	+
428	-	+	-	+	-	+	-	-	-	Emaciated	+
340	+	+	+	+	+	-	-	-	-	Emaciated	+
337	-	-	+	+	+	-	-	-	-	Emaciated	+
307	-	+	-	+	+	+	-	-	-	Emaciated	+
352	-	+	-	-	-	+	-	-	-	Emaciated, tumors in intestines	+
402	-	+	+	-	+	-	-	-	-		+

**Individual Bird Necropsy Data
Marek's Challenge – Negative Controls (Group 5)
Gross Lesions Associated with MDV**

Bird ID#	Paralysis	Liver	Heart	Spleen	Proven.	Kidneys	Gonads	Nerves	Skin	Comments	Result (+ or -)
163	-	-	-	-	-	-	-	-	-		-
345	-	-	-	-	-	-	-	-	-		-
168	-	-	-	-	-	-	-	-	-		-
415	-	-	-	-	-	-	-	-	-		-
343	-	-	-	-	-	-	-	-	-		-
375	-	-	-	-	-	-	-	-	-		-
457	-	-	-	-	-	-	-	-	-		-
411	-	-	-	-	-	-	-	-	-		-
475	-	-	-	-	-	-	-	-	-		-
349	-	-	-	-	-	-	-	-	-		-
389	-	-	-	-	-	-	-	-	-		-
453	-	-	-	-	-	-	-	-	-		-
462	-	-	-	-	-	-	-	-	-		-
447	-	-	-	-	-	-	-	-	-		-
417	-	-	-	-	-	-	-	-	-		-
468	-	-	-	-	-	-	-	-	-		-
487	-	-	-	-	-	-	-	-	-		-
446	-	-	-	-	-	-	-	-	-		-
476	-	-	-	-	-	-	-	-	-		-
376	-	-	-	-	-	-	-	-	-		-
305	-	-	-	-	-	-	-	-	-		-
320	-	-	-	-	-	-	-	-	-		-
430	-	-	-	-	-	-	-	-	-		-
464	-	-	-	-	-	-	-	-	-		-
418	-	-	-	-	-	-	-	-	-		-

**Individual Bird Post-Challenge Data
Newcastle Challenge – Vaccinates (Group 2B)**

Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Result (+ or -)
Bird ID#															
363	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
331	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
444	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
406	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
328	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
424	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
485	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
392	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
397	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
396	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
500	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
433	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
357	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
435	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
421	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
364	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
355	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
404	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
383	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
327	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
365	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
379	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
329	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
492	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
471	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
334	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
407	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
314	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
483	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
315	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
398	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
488	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-

Bird Observations: (N) Normal; (D) Dead; (U) Uncoordinated; (P) Paralyzed

**Individual Bird Post-Challenge Data
Newcastle Challenge – Positive Controls (Group 4)**

Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Result (+ or -)
Bird ID#															
304	N	N	N	D											+
312	N	N	D												+
354	N	N	P	D											+
472	N	N	D												+
467	N	N	P	D											+
399	N	N	P	D											+
341	N	N	P	D											+
458	N	N	P	D											+
413	N	U	D												+
434	N	N	N	D											+
301	N	N	N	P	D										+
463	N	N	D												+

Bird Observations: (N) Normal; (D) Dead; (U) Uncoordinated; (P) Paralyzed

Study Type	Efficacy																		
Pertaining to	Newcastle disease virus (NDV)																		
Study Purpose	To demonstrate efficacy against NDV 60 weeks after vaccination																		
Product Administration	Subcutaneous																		
Study Animals	34 specific-pathogen-free chickens at day-of-age, 22 vaccinates and 12 placebo controls																		
Challenge Description	Challenged with NDV at 60 weeks post-vaccination																		
Interval observed after challenge	Observed for clinical signs for 14 days post-challenge																		
Results	<p>Summary of results:</p> <table border="1" data-bbox="555 887 1358 1077"> <thead> <tr> <th rowspan="3">NDV CHALLENGE</th> <th colspan="4">Treatment Group</th> </tr> <tr> <th colspan="2">Vaccinates</th> <th colspan="2">Placebos</th> </tr> <tr> <th>Number positive/total</th> <th>Percent Protection</th> <th>Number positive/total</th> <th>Percent Protection</th> </tr> </thead> <tbody> <tr> <td>60 weeks</td> <td>1/22</td> <td>95</td> <td>12/12</td> <td>0</td> </tr> </tbody> </table> <p>Requirements per 9 CFR 113.329 were met.</p> <p>Raw data attached.</p>	NDV CHALLENGE	Treatment Group				Vaccinates		Placebos		Number positive/total	Percent Protection	Number positive/total	Percent Protection	60 weeks	1/22	95	12/12	0
NDV CHALLENGE	Treatment Group																		
	Vaccinates		Placebos																
	Number positive/total	Percent Protection	Number positive/total	Percent Protection															
60 weeks	1/22	95	12/12	0															
USDA Approval Date	July 13, 2011																		

**Individual Bird Post-Challenge Data
(60 Week Challenge - Vaccinates)**

Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Result
Bird ID															
806	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
867	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
884	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
896	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
179	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
186	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
188	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
606	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
612	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
626	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
636	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
639	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
657	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
693	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
704	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
716	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
733	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
747	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
763	N	N	N	N	U	D									-
778	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
783	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-
800	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-

Bird Observations: (N) No clinical signs of Newcastle Disease
(D) Dead; (U) Uncoordinated; (P) Paralyzed

**Individual Bird Post-Challenge Data
(60 Week Challenge -Placebos)**

Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Result
Bird ID															
632	N	N	N	P	D										+
681	N	N	N	N	N	P	D								+
701	N	N	N	N	U	P	P	P	D	26/2/2015					+
723	N	N	N	P	D										+
728	N	N	N	N	U	D									+
742	N	N	N	P	D										+
746	N	N	N	U	D										+
765	N	N	N	N	N	D									+
813	N	N	N	N	U	D									+
825	N	N	N	N	N	U	U	U	U	P	P	P	P	P	+
837	N	N	N	N	N	U	U	U	P	P	P	P	P	P	+
839	N	N	N	U	D										+

Bird Observations: (N) No clinical signs of Newcastle Disease
(D) Dead; (U) Uncoordinated; (P) Paralyzed

Study Type	Efficacy																		
Pertaining to	Newcastle disease virus (NDV)																		
Study Purpose	To demonstrate efficacy against NDV 10 weeks after vaccination																		
Product Administration	In ovo																		
Study Animals	45 specific-pathogen-free 18-day-old embryos , 33 vaccinates and 11 placebo controls																		
Challenge Description	Challenged with NDV at 10 weeks post-vaccination (chickens 10 weeks of age)																		
Interval observed after challenge	Observed for clinical signs for 14 days post-challenge																		
Results	<p>Summary of results:</p> <table border="1" data-bbox="555 887 1358 1077"> <thead> <tr> <th rowspan="3">NDV CHALLENGE</th> <th colspan="4">Treatment Group</th> </tr> <tr> <th colspan="2">Vaccinates</th> <th colspan="2">Controls</th> </tr> <tr> <th>Number positive/total</th> <th>Percent Protection</th> <th>Number positive/total</th> <th>Percent Protection</th> </tr> </thead> <tbody> <tr> <td>10 weeks</td> <td>2/33</td> <td>94</td> <td>11/11</td> <td>0</td> </tr> </tbody> </table> <p>Requirements per 9 CFR 113.329(c)(3) were met.</p> <p>Raw data attached.</p>	NDV CHALLENGE	Treatment Group				Vaccinates		Controls		Number positive/total	Percent Protection	Number positive/total	Percent Protection	10 weeks	2/33	94	11/11	0
NDV CHALLENGE	Treatment Group																		
	Vaccinates		Controls																
	Number positive/total	Percent Protection	Number positive/total	Percent Protection															
10 weeks	2/33	94	11/11	0															
USDA Approval Date	October 26, 2007																		

**Individual Bird Post-Challenge Data
(10 Week Challenge – Vaccinates and Controls)**

ID	Group [¥]	DPC1*	DPC2	DPC3	DPC4	DPC5	DPC6	DPC7	DPC8	DPC9	DPC10	DPC11	DPC12	DPD13	DPC14	Result	
2297	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2300	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2301	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2305	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2309	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2311	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2315	3	N	N	I	D											+	
2317	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2319	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2325	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2326	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2295	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2307	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2308	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2310	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2316	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2318	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2320	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2322	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2295	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2298	3	N	N	I	D											+	
2299	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2302	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2304	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2306	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2312	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2313	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2314	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2321	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2323	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2324	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2328	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2329	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	
2239	gp 3 cont	N	N	N	P	bird was euthanized										+	
2240	gp 3 cont	N	N	I	D											+	
2236	gp 3 cont	N	N	I	D											+	
2237	gp 3 cont	N	N	I	D											+	
2241	gp 3 cont	N	N	P	D											+	
2242	gp 3 cont	N	N	I	P	bird was euthanized										+	
2244	gp 3 cont	N	N	I	D											+	
2245	gp 3 cont	N	N	N	P	bird was euthanized										+	
2238	gp 3 cont	N	N	N	P	bird was euthanized										+	
2243	gp 3 cont	N	N	N	N	P	bird was euthanized										+
2246	gp 3 cont	N	N	I	D	N										+	

BIRD OBSERVATIONS: (N) Normal; (D) Deaf; (I) Incoordinated; (P) Paralyzed

¥ Group 3 is vaccinate group, gp 3 cont is placebo control group
*DPC is day post-challenge

Study Type	Safety																																
Pertaining to	ALL																																
Study Purpose	To demonstrate safety of product under typical field conditions																																
Product Administration	One dose was administered by the subcutaneous route to 1-day old chickens.																																
Study Animals	A total of 333,196 broiler and layer chickens, representing 3 distinct geographical locations.																																
Challenge Description	N/A																																
Interval observed after challenge	Layer chickens (Site 1 and 2) were observed daily for mortality through 8 weeks of age. Broiler chickens (Site 3) were observed until harvest.																																
Results	<table border="1"> <thead> <tr> <th>Site</th> <th>Group</th> <th>Total Placed</th> <th>% Mortality</th> <th>Condemnation Rates</th> </tr> </thead> <tbody> <tr> <td rowspan="2">1</td> <td>Vaccinate</td> <td>99,900</td> <td>2.32</td> <td>--</td> </tr> <tr> <td>Control</td> <td>99,900</td> <td>2.93</td> <td>--</td> </tr> <tr> <td rowspan="2">2</td> <td>Vaccinate</td> <td>17,798</td> <td>0.79</td> <td>--</td> </tr> <tr> <td>Control</td> <td>17,598</td> <td>0.98</td> <td>--</td> </tr> <tr> <td rowspan="2">3</td> <td>Vaccinate</td> <td>49,000</td> <td>9.89</td> <td>0.12</td> </tr> <tr> <td>Control</td> <td>49,900</td> <td>6.61</td> <td>0.24</td> </tr> </tbody> </table> <p>No adverse reactions attributable to vaccination with the test article were reported.</p>	Site	Group	Total Placed	% Mortality	Condemnation Rates	1	Vaccinate	99,900	2.32	--	Control	99,900	2.93	--	2	Vaccinate	17,798	0.79	--	Control	17,598	0.98	--	3	Vaccinate	49,000	9.89	0.12	Control	49,900	6.61	0.24
Site	Group	Total Placed	% Mortality	Condemnation Rates																													
1	Vaccinate	99,900	2.32	--																													
	Control	99,900	2.93	--																													
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	Control	17,598	0.98	--																													
3	Vaccinate	49,000	9.89	0.12																													
	Control	49,900	6.61	0.24																													
USDA Approval Date	February 22, 2011																																

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety of product under typical field conditions
Product Administration	<i>In ovo</i>
Study Animals	Chicken
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	January 18, 2007