



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	17H1.R2
True Name	Marek's Disease-Newcastle Disease Vaccine, Serotypes 2 & 3, Live Virus, Live Marek's Disease Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Innofusion-ND-SB - MSD Salud Animal Columbia S.A.S. Innofusion-ND-SB - No distributor specified Merck Animal Health
Date of Compilation Summary	November 19, 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	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="552 884 1356 1075"> <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	-	
2296	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) Deag; (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	<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