Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	1A89.R1
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)	Not Listed - No distributor specified
Date of Compilation Summary	June 30, 2020

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy
Pertaining to	Infectious Bursal Disease Virus
Study Purpose	Evaluate the efficacy against Infectious Bursal Disease (IBD)
Product Administration	One dose administered by the subcutaneous route
Study Animals	Day-old chicks divided into two groups: Group 1, 35 chicks, vaccine treatment Group 4, 20 chicks, diluent inoculated challeneged controls
Challenge Description	Challenged with Standard IBD virus at 28 days of age.
Interval observed after challenge	Observed for clinical signs for 3 days post-challenge. All birds were examined for gross lesions 3 days post-challenge.
Results	Summary of results: Vaccinates and controls were evaluated for clinical signs & gross lesions related to infectious bursal disease per criteria in 9 CFR 113.331(c). Birds positive for Infectious Bursal Disease: Group 1: 0/35 Group 4: 20/20 Requirements per 9 CFR 113.331 were met Raw data attached
USDA Approval Date	May 23, 2016

Table 1: Individual bird data receiving vaccine

Bird ID	Treatment Group	Positive For IBDV
606	1	No
607	1	No
609	1	No
616	1	No
630	1	No
655	1	No
669	1	No
679	1	No
695	1	No
703	1	No
710	1	No
601	1	No
610	1	No
615	1	No
627	1	No
639	1	No
644	1	No
657	1	No
661	1	No
678	1	No
691	1	No
701	1	No
702	1	No
612	1	No
624	1	No
626	1	No
643	1	No
654	1	No
660	1	No
663	1	No
697	1	No
699	1	No
707	1	No
717	1	No
721	1	No
Total		**35**
Percent Protection		**100%**

Table 2: Individual bird data receiving diluent

Bird ID	Treatment Group	Positive For IBDV
603	4	Yes
611	4	Yes
628	4	Yes
635	4	Yes
638	4	Yes
652	4	Yes
666	4	Yes
673	4	Yes
675	4	Yes
676	4	Yes
677	4	Yes
681	4	Yes
690	4	Yes
708	4	Yes
709	4	Yes
712	4	Yes
715	4	Yes
718	4	Yes
722	4	Yes
725	4	Yes
Total		**20**
Percent Protection		**0%**

Study Type	Efficacy
Pertaining to	Infectious Bursal Disease Virus
Study Purpose	Evaluate the efficacy against Infectious Bursal Disease (IBD)
Product Administration	One dose administered *in ovo* at 18 days of embryonation
Study Animals	Group 1: 35 embryos, vaccine Group 4: 20 embryos, diluent inoculated controls
Challenge Description	Challenged with infectious bursal disease virus at 28 days of age.
Interval observed after challenge	Observed for clinical signs for 3 days post-challenge. All birds were examined for gross lesions 3 days post-challenge.
Results	Summary of results: Vaccinates and controls were evaluated for clinical signs & gross lesions related to infectious bursal disease per criteria in 9 CFR 113.331(c). Birds positive for Infectious Bursal Disease: Group 1: 1/35 Group 4: 18/20 Requirements per 9 CFR 113.331 were met Raw data attached
USDA Approval Date	September 9, 2016

Table 1: Individual bird data receiving vaccine

Bird ID	Treatment Group	Positive For IBDV
803	1	No
805	1	No
810	1	No
811	1	No
818	1	No
821	1	No
825	1	No
827	1	No
828	1	No
837	1	No
839	1	No
840	1	No
849	1	No
853	1	No
855	1	No
857	1	No
860	1	No
861	1	No
862	1	No
864	1	No
871	1	No
874	1	No
878	1	No
879	1	No
880	1	No
888	1	No
890	1	No
893	1	No
901	1	No
906	1	No
912	1	No
913	1	No
919	1	No
920	1	No
925	1	Yes
Total		35
Percent Protection		97%

Table 2: Individual bird data receiving diluent

Bird ID	Treatment Group	Positive For IBDV
802	4	Yes
809	4	Yes
815	4	Yes
817	4	Yes
852	4	No
854	4	Yes
858	4	Yes
863	4	Yes
866	4	Yes
867	4	Yes
877	4	Yes
889	4	Yes
892	4	Yes
895	4	Yes
896	4	Yes
897	4	Yes
899	4	Yes
908	4	Yes
917	4	Yes
922	4	No
Total		20
Percent Protection		10%

Study Type	Efficacy
Pertaining to	Infectious Bursal Disease Virus
Study Purpose	To demonstrate effectiveness against disease caused by Infectious Bursal Disease (IBD) Variant E
Product Administration	One dose administered *in ovo* at 18 days of embryonation.
Study Animals	Group 1: 35 embryos, vaccine treatment Group 2: 35 embryos, diluent inoculated challenged controls
Challenge Description	Challenged with IBD Variant E strain at 28 days of age.
Interval observed after challenge	Observed for clinical signs for 10 days post-challenge. Bursal/body weight ratios were determined for each bird 10 days post-challenge.
Results	Summary of results: Birds positive for Infectious Bursal Disease: Group 1: 3/35 Group 2: 35/35 Requirements per 9 CFR 113.331(c)(3)(ii) were met. Raw data attached
USDA Approval Date	April 15, 2019

Individual Bird Necropsy Data

Bird Count	Treatment Group	Bird ID #	Body Weight (g)	Bursa Weight (g)	Sex	Bursa/BW Ratio	Positive	Negative
1	1	896	496.7	0.60	F	1.21	1	0
2	1	897	628.7	3.71	M	5.90	0	1
3	1	898	396.7	1.02	F	2.57	1	0
4	1	899	638.3	3.51	M	5.50	0	1
5	1	900	474.3	2.01	M	4.24	0	1
6	1	905	481.1	4.08	M	8.48	0	1
7	1	906	409.4	2.26	F	5.52	0	1
8	1	909	449.3	2.98	F	6.63	0	1
9	1	916	550.0	2.29	M	4.16	0	1
10	1	917	501.4	1.86	M	3.71	0	1
11	1	924	428.6	1.97	F	4.60	0	1
12	1	930	497.0	2.61	M	5.25	0	1
13	1	931	378.3	2.15	F	5.68	0	1
14	1	936	452.9	2.58	F	5.70	0	1
15	1	937	490.8	1.88	M	3.83	0	1
16	1	938	535.1	2.42	M	4.52	0	1
17	1	944	475.0	3.05	M	6.42	0	1
18	1	952	534.6	2.72	F	5.09	0	1
19	1	953	485.1	0.79	F	1.63	1	0
20	1	961	471.5	2.47	M	5.24	0	1
21	1	962	463.5	2.66	F	5.74	0	1
22	1	964	489.3	1.92	F	3.92	0	1
23	1	968	472.5	3.25	F	6.88	0	1
24	1	970	471.9	1.56	M	3.31	0	1
25	1	972	438.6	2.26	F	5.15	0	1
26	1	973	436.7	2.97	M	6.80	0	1
27	1	974	467.1	1.37	M	2.93	0	1
28	1	975	418.9	3.10	F	7.40	0	1
29	1	977	423.0	1.98	F	4.68	0	1
30	1	981	572.5	1.68	M	2.93	0	1
31	1	986	486.9	2.67	M	5.48	0	1
32	1	988	516.8	2.14	F	4.14	0	1
33	1	995	447.6	2.19	F	4.89	0	1
34	1	997	606.4	4.57	M	7.54	0	1
35	1	998	390.7	2.00	F	5.12	0	1

Individual Bird Necropsy Data (continued)

Bird Count	Treatment Group	Bird ID #	Body Weight (g)	Bursa Weight (g)	Sex	Bursa/BW Ratio	Positive	Negative
1	2	901	491.3	1.03	M	2.10	1	0
2	2	902	522.8	1.23	F	2.35	1	0
3	2	903	344.4	0.45	F	1.31	1	0
4	2	904	451.9	0.76	M	1.68	1	0
5	2	907	349.6	0.66	F	1.89	1	0
6	2	908	431.8	0.65	F	1.51	1	0
7	2	911	447.1	0.70	F	1.57	1	0
8	2	914	517.2	0.84	M	1.62	1	0
9	2	922	499.7	0.65	M	1.30	1	0
10	2	923	446.4	0.68	F	1.52	1	0
11	2	925	374.7	0.49	F	1.31	1	0
12	2	926	496.0	0.43	M	0.87	1	0
13	2	927	377.9	0.45	M	1.19	1	0
14	2	933	492.7	0.88	M	1.79	1	0
15	2	939	444.0	0.79	M	1.78	1	0
16	2	942	478.8	0.65	M	1.36	1	0
17	2	947	396.3	0.51	F	1.29	1	0
18	2	948	449.4	0.63	M	1.40	1	0
19	2	949	425.3	0.61	F	1.43	1	0
20	2	950	475.0	0.61	M	1.28	1	0
21	2	955	428.5	0.57	F	1.33	1	0
22	2	957	491.3	0.72	F	1.47	1	0
23	2	960	401.1	0.71	F	1.77	1	0
24	2	963	378.1	0.40	F	1.06	1	0
25	2	965	516.0	1.05	M	2.03	1	0
26	2	966	367.5	0.40	F	1.09	1	0
27	2	967	468.2	0.63	M	1.35	1	0
28	2	971	473.8	0.62	M	1.31	1	0
29	2	978	511.9	1.03	F	2.01	1	0
30	2	980	529.2	0.99	M	1.87	1	0
31	2	982	383.2	0.48	F	1.25	1	0
32	2	983	399.0	0.59	M	1.48	1	0
33	2	987	416.7	0.57	M	1.37	1	0
34	2	993	451.8	0.72	F	1.59	1	0
35	2	1000	378.3	0.69	F	1.82	1	0

Study Type	Efficacy
Pertaining to	Infectious Bursal Disease Virus
Study Purpose	To demonstrate effectiveness against disease caused by variant Infectious Bursal Disease (IBD) Variant E
Product Administration	One dose administered by the subcutaneous route.
Study Animals	Day-old chicks divided into two groups: Group 1: 34 chicks, vaccine treatment Group 2: 35 chicks, diluent inoculated challenged controls
Challenge Description	Challenged with IBD variant E strain at 28 days of age.
Interval observed after challenge	Observed for clinical signs for 10 days post-challenge. Bursal/body weight ratios were determined for each bird 10 days post-challenge.
Results	Summary of results: Birds positive for Infectious Bursal Disease: Group 1: 1/34 Group 2: 35/35 Requirements per 9 CFR 113.331(c)(3)(ii) were met. Raw data attached
USDA Approval Date	April 16, 2019

Individual Bird Necropsy Data

Bird Count	Treatment Group	Bird ID #	Body Weight (g)	Bursa Weight (g)	Sex	Bursa/BW Ratio	Positive	Negative
1	1	402	451.3	1.56	M	3.46	0	1
2	1	408	448.8	3.75	F	8.36	0	1
3	1	413	483.3	1.57	F	3.25	0	1
4	1	415	429.2	1.32	F	3.08	0	1
5	1	422	575.7	3.86	M	6.70	0	1
6	1	424	440.3	2.17	F	4.93	0	1
7	1	427	290.5	0.54	F	1.86	1	0
8	1	429	525.8	2.64	M	5.02	0	1
9	1	438	480.3	2.08	F	4.33	0	1
10	1	439	462.5	2.50	F	5.41	0	1
11	1	440	595.1	2.81	M	4.72	0	1
12	1	442	404.2	2.17	F	5.37	0	1
13	1	443	554.8	2.16	M	3.89	0	1
14	1	445	526.6	3.11	M	5.91	0	1
15	1	455	509.0	2.97	F	5.83	0	1
16	1	459	460.1	2.02	F	4.39	0	1
17	1	467	489.9	3.10	M	6.33	0	1
18	1	470	593.9	2.44	M	4.11	0	1
19	1	471	610.1	3.61	M	5.92	0	1
20	1	474	453.2	1.81	M	3.99	0	1
21	1	475	523.5	2.56	M	4.89	0	1
22	1	476	489.3	2.62	M	5.35	0	1
23	1	478	564.6	2.47	M	4.37	0	1
24	1	480	379.6	1.61	F	4.24	0	1
25	1	486	459.3	1.75	F	3.81	0	1
26	1	487	449.1	1.94	F	4.32	0	1
27	1	489	521.3	2.73	M	5.24	0	1
28	1	491	465.6	2.81	M	6.04	0	1
29	1	492	588.9	2.34	M	3.97	0	1
30	1	495	529.6	3.17	M	5.99	0	1
31	1	499	468.5	2.39	F	5.10	0	1
32	1	503	556.8	1.99	M	3.57	0	1
33	1	504	548.5	2.39	M	4.36	0	1
34	1	505	475.7	2.66	F	5.59	0	1

Individual Bird Necropsy Data (continued)

Bird Count	Treatment Group	Bird ID #	Body Weight (g)	Bursa Weight (g)	Sex	Bursa/BW Ratio	Positive	Negative
1	2	404	376.6	0.77	F	2.04	1	0
2	2	411	506.9	0.67	M	1.32	1	0
3	2	412	568.3	0.78	M	1.37	1	0
4	2	417	431.8	0.70	M	1.62	1	0
5	2	420	468.6	1.03	M	2.20	1	0
6	2	425	369.7	0.87	F	2.35	1	0
7	2	426	330.7	0.40	F	1.21	1	0
8	2	428	375.9	0.59	F	1.57	1	0
9	2	430	408.8	0.61	F	1.49	1	0
10	2	432	356.1	0.54	F	1.52	1	0
11	2	433	448.7	0.79	M	1.76	1	0
12	2	435	418.0	0.79	F	1.89	1	0
13	2	437	451.4	0.40	M	0.89	1	0
14	2	448	453.1	0.49	F	1.08	1	0
15	2	450	362.4	0.62	F	1.71	1	0
16	2	453	379.2	0.68	F	1.79	1	0
17	2	454	460.0	0.49	F	1.07	1	0
18	2	456	405.3	0.35	F	0.86	1	0
19	2	457	521.5	0.93	M	1.78	1	0
20	2	461	417.2	0.75	F	1.80	1	0
21	2	462	476.9	0.81	M	1.70	1	0
22	2	463	538.2	0.70	M	1.30	1	0
23	2	464	463.8	0.46	F	0.99	1	0
24	2	465	537.6	0.55	M	1.02	1	0
25	2	469	397.1	0.59	F	1.49	1	0
26	2	472	384.6	0.31	F	0.81	1	0
27	2	473	476.3	0.74	F	1.55	1	0
28	2	477	357.3	0.48	F	1.34	1	0
29	2	481	442.4	0.63	M	1.42	1	0
30	2	482	466.2	0.92	M	1.97	1	0
31	2	488	431.8	0.56	F	1.30	1	0
32	2	493	437.5	0.75	F	1.71	1	0
33	2	496	383.1	0.66	F	1.72	1	0
34	2	498	412.3	0.65	M	1.58	1	0
35	2	501	436.1	0.53	M	1.22	1	0

Study Type	Efficacy
Pertaining to	Marek's Disease Virus
Study Purpose	Evaluate the efficacy against Marek's Disease Virus (MDV)
Product Administration	One dose administered *in ovo* at 18 days of embryonation
Study Animals	Group 3: 35 embryos, vaccine Group 4: 35 embryos, diluent inoculated challenged controls Group 5: 25 embryos, diluent inoculated non-challenged controls
Challenge Description	Challenged with Marek's disease virus at 5 days of age
Interval observed after challenge	Observed daily for clinical signs and evaluated for gross lesions at 7 weeks of age.
Results	Summary of results: Vaccinates and controls were evaluated for clinical signs related to Marek's disease per criteria in 9 CFR 113.330. Birds positive for Marek's Disease: Group 3: 6/35 Group 4: 33/34 Group 5: 0/25 Requirements per 9 CFR 113.330 were met Raw data attached
USDA Approval Date	October 31, 2016

Group 3: Individual Animal Data

Wing Tag No.	Heart	Liver	Spleen	Gonads	Kidneys	Prov.	Paralysis	Result	End of Study Status	Comments
1305	0	0	0	0	0	0	0	0	Alive	
1308	1	1	1	0	1	1	0	1	Alive	Breast tumor
1310	0	0	0	0	0	0	0	0	Alive	
1312	0	0	0	0	0	0	0	0	Alive	
1329	0	0	0	0	0	0	0	0	Alive	
1339	0	0	0	0	0	0	0	0	Alive	
1351	0	0	0	0	0	0	0	0	Alive	
1369	0	0	0	0	0	0	0	0	Alive	
1384	0	1	0	0	0	0	0	1	Alive	Sick
1402	1	1	1	0	1	1	0	1	Dead	Swollen comb, feet, hocks, euthanized
1406	0	0	0	0	0	0	0	0	Alive	
1440	0	0	0	0	0	0	0	0	Alive	
1445	0	0	0	0	0	0	0	0	Alive	
1450	0	0	0	0	0	0	0	0	Alive	
1453	0	0	0	0	0	0	0	0	Alive	
1455	0	0	0	0	0	0	0	0	Alive	
1460	0	0	0	0	0	0	0	0	Alive	
1463	1	1	1	1	1	0	0	1	Dead	Euthanized
1465	0	0	0	0	0	0	0	0	Alive	
1468	0	0	0	0	0	0	0	0	Alive	
1471	0	0	0	0	0	0	0	0	Alive	
1477	0	0	0	0	0	0	0	0	Alive	
1484	0	0	0	0	0	0	0	0	Alive	
1485	0	0	0	0	0	0	0	0	Alive	
1495	0	0	0	0	0	0	0	0	Alive	
1499	0	0	0	0	0	0	0	0	Alive	
1503	0	0	0	0	0	0	0	0	Alive	
1507	0	0	0	0	0	1	0	1	Dead	Dead
1509	0	0	0	0	0	0	0	0	Alive	
1518	0	0	0	0	0	0	0	0	Alive	
1527	0	0	0	0	0	0	0	0	Alive	
1530	0	0	1	1	0	0	0	1	Alive	Intestines-tumor
1534	0	0	0	0	0	0	0	0	Alive	
1544	0	0	0	0	0	0	0	0	Alive	
1552	0	0	0	0	0	0	0	0	Alive	

Result: "0" indicates no lesions of Marek's disease
"1" indicates lesions of Marek's disease were observed

Group 4: Individual Animal Data

Wing Tag No.	Heart	Liver	Spleen	Gonads	Kidneys	Prov.	Paralysis	Result	End of Study Status	Comments
1280	1	0	1	0	1	0	0	1	Dead	Red hocks,euthanized
1288	1	1	1	0	1	1	0	1	Alive	Sick
1306	1	1	1	0	1	1	0	1	Dead	Swollen black comb
1316	1	1	1	1	1	1	0	1	Dead	Swollen red hocks, black comb, euthanized..
1319	1	1	1	0	1	1	0	1	Dead	Breast tumor, swollen hocks, black comb, euthanized
1321	1	1	1	0	0	1	0	1	Alive	Intestines-tumor, sick on
1332	1	1	1	1	1	1	0	1	Dead	Dead
1346	1	0	1	1	1	1	0	1	Dead	Swollen hocks, red blotchy foot, euthanized
1353	1	1	1	0	1	1	0	1	Dead	Emaciated, dead
1367	1	1	1	0	1	0	0	1	Dead	Red blotchy skin, swollen comb, euthanized
1370	1	0	1	0	0	1	0	1	Dead	Euthanized
1371	1	1	1	0	0	1	0	1	Dead	Comb & hocks swollen, euthanized
1373	1	0	1	0	1	1	1	1	Dead	Swollen comb, euthanized
1375	0	0	1	0	0	0	0	1	Alive	
1379	1	0	1	0	0	0	0	1	Alive	Sick , Intestines - tumor
1387	1	1	1	0	1	0	0	1	Dead	Blotchy red hocks, euthanized
1388	1	1	1	0	0	1	0	1	Dead	Euthanized
1404	0	1	1	0	1	0	0	1	Dead	Euthanized
1410	0	0	0	0	0	1	1	1	Dead	Euthanized
1411	1	1	1	1	1	1	0	1	Dead	Swollen red hocks, euthanized
1419	1	1	1	0	1	0	0	1	Dead	Euthanized
1420	1	1	1	0	1	1	0	1	Dead	Euthanized
1442	1	1	1	0	1	0	0	1	Dead	Euthanized
1444	1	1	1	0	0	1	0	1	Dead	Euthanized
1459	1	1	1	1	1	1	0	1	Dead	Euthanized
1480	1	1	1	0	0	1	0	1	Dead	Weak, huddled, euthanized
1483	0	1	1	0	0	1	0	1	Alive	
1487	1	1	1	0	1	0	0	1	Dead	Dead
1501	0	0	1	1	1	1	1	1	Dead	Red hock, euthanized
1511	0	0	0	0	0	0	0	1	Dead	Huddled, ruffled, euthanized
1514	1	0	1	0	0	1	0	1	Dead	Black comb, euthanized
1516	0	0	0	0	0	0	0	0	Alive	
1517	1	0	1	1	1	1	0	1	Dead	Euthanized
1553	1	1	0	1	0	0	0	1	Alive	Sick, Intestines-tumor

Result: “0” indicates no lesions of Marek’s disease
“1” indicates lesions of Marek’s disease were observed

Group 5: Individual Animal Data

Wing Tag No.	Heart	Liver	Spleen	Gonads	Kidneys	Prov.	Paralysis	Result	End of Study Status	Comments
1286	0	0	0	0	0	0	0	0	Alive	
1307	0	0	0	0	0	0	0	0	Alive	
1309	0	0	0	0	0	0	0	0	Alive	
1327	0	0	0	0	0	0	0	0	Alive	
1333	0	0	0	0	0	0	0	0	Alive	
1336	0	0	0	0	0	0	0	0	Alive	
1363	0	0	0	0	0	0	0	0	Alive	
1364	0	0	0	0	0	0	0	0	Alive	
1372	0	0	0	0	0	0	0	0	Alive	
1391	0	0	0	0	0	*	*	0	Alive	
1393	0	0	0	0	0	0	0	0	Alive	
1427	0	0	0	0	0	0	0	0	Alive	
1428	0	0	0	0	0	0	0	0	Alive	
1434	0	0	0	0	0	0	0	0	Alive	
1441	0	0	0	0	0	0	0	0	Alive	
1466	0	0	0	0	0	0	0	0	Alive	
1493	0	0	0	0	0	0	0	0	Alive	
1505	0	0	0	0	0	0	0	0	Alive	
1506	0	0	0	0	0	0	0	0	Alive	
1513	0	0	0	0	0	0	0	0	Alive	
1524	0	0	0	0	0	0	0	0	Alive	
1545	0	0	0	0	0	0	0	0	Alive	
1546	0	0	0	0	0	0	0	0	Alive	
1547	0	0	0	0	0	0	0	0	Alive	
1551	0	0	0	0	0	0	0	0	Alive	

*not recorded

Result: "0" indicates no lesions of Marek's disease
"1" indicates lesions of Marek's disease were observed

Study Type	Efficacy
Pertaining to	Marek's Disease Virus
Study Purpose	Evaluate the efficacy against Marek's Disease Virus (MDV)
Product Administration	One dose administered subcutaneous route
Study Animals	Day-old chicks divided into three groups: Group 1, 35 chicks, vaccine treatment Group 2, 34 chicks, diluent inoculated challenged controls Group 3, 25 chicks, diluent inoculated non-challenged controls
Challenge Description	Challenged with Marek's disease virus at 5 days of age.
Interval observed after challenge	Observed daily for clinical signs and evaluated for gross lesions at 7 weeks of age.
Results	Summary of results: Vaccinates and controls were evaluated for clinical signs related to Marek's disease per criteria in 9 CFR 113.330. Birds positive for Marek's Disease: Group 1: 5/34 Group 2: 34/34 Group 3: 0/25 Requirements per 9 CFR 113.330 were met Raw data attached
USDA Approval Date	December 5, 2016

Group 1: Individual Animal Data

Wing Tag No.	Heart	Liver	Spleen	Gonads	Kidneys	Prov.	Paralysis	Result	End of Study Status	Comments
496	0	0	0	0	0	0	0	0	Alive	
502	0	0	0	0	0	0	0	0	Alive	
504	0	0	0	0	0	0	0	0	Alive	
508	1	1	1	1	1	1	0	1	Alive	
514	0	0	0	0	0	0	0	0	Alive	
515	0	0	0	0	0	0	0	0	Alive	
518	0	0	0	0	0	0	0	0	Alive	
521	0	0	0	0	0	0	0	0	Alive	
524	0	0	0	0	0	0	0	0	Alive	
531	0	0	0	0	0	0	0	0	Alive	
532	0	0	0	1	0	0	0	1	Alive	
534	0	0	0	0	0	0	0	0	Alive	
536	0	0	0	0	0	0	0	0	Alive	
537	0	0	0	0	0	0	0	0	Alive	
538	0	0	0	0	0	0	0	0	Alive	
543	0	0	0	0	0	0	0	0	Alive	
546	0	0	0	0	0	0	0	0	Alive	
550	0	0	0	0	0	0	0	0	Alive	
553	0	0	0	0	0	0	0	0	Alive	
554	0	0	0	0	0	0	0	0	Alive	
556	0	0	0	0	0	0	0	0	Alive	
558	0	0	0	0	0	0	0	0	Alive	
560	0	0	0	0	0	0	0	0	Alive	
571	0	0	0	0	0	0	0	0	Alive	
573	0	0	0	0	0	0	0	0	Alive	
574	0	0	0	0	0	0	0	0	Alive	
576	0	0	0	0	0	0	0	0	Alive	
578	1	0	0	0	0	0	0	1	Alive	
579	0	0	0	0	0	0	0	0	Alive	
581	0	0	0	0	0	0	0	0	Alive	
582	0	0	0	0	0	0	0	0	Alive	
584	0	1	1	1	1	0	0	1	Alive	
586	0	0	0	1	0	0	0	1	Alive	
588	0	0	0	0	0	0	0	0	Alive	

Result: "0" indicates no lesions of Marek's disease
"1" indicates lesions of Marek's disease were observed

Group 2: Individual Animal Data

Wing Tag No.	Heart	Liver	Spleen	Gonads	Kidneys	Prov.	Paralysis	Result	End of Study Status	Comments
497	1	0	0	0	1	0	0	1	Dead	Blotchy legs, dead
498	1	1	1	0	0	1	0	1	Alive	
499	1	0	1	0	1	0	0	1	Dead	Hemorrhages on wings, legs
505	1	0	1	1	0	1	0	1	Alive	Intestine - tumor
506	1	1	1	0	1	1	1	1	Dead	Emaciated/euthanize
507	1	0	1	0	1	1	0	1	Dead	Injured toe, euthanized
509	1	1	1	0	1	1	0	1	Dead	Blotchy legs, euthanized
511	0	0	0	0	0	0	0	1	Dead	Swollen, spongy head, black comb, blotchy legs
512	0	0	1	0	0	1	0	1	Alive	
519	1	1	1	0	1	0	0	1	Dead	Red skin, euthanized
520	1	1	1	0	0	0	0	1	Alive	Sick
525	1	1	1	0	1	0	0	1	Dead	Emaciated/euthanize
530	1	1	1	1	1	1	0	1	Dead	Swollen, blotchy hocks, swollen black comb, euthanized
535	0	1	1	0	0	0	0	1	Dead	Intestines adhered, red legs, black comb
540	1	0	1	1	0	1	0	1	Alive	Sick
541	1	1	1	0	1	0	0	1	Dead	Emaciated
542	1	1	1	0	1	1	-	1	Alive	Sick
544	0	1	1	1	1	0	0	1	Dead	Blk comb/euthanized
547	1	0	1	0	0	0	0	1	Dead	Blotchy hocks, swollen comb, euthanized
549	1	1	1	0	1	1	0	1	Alive	Intes
557	1	1	1	0	1	1	0	1	Dead	Black comb, red blotchy hocks. red skin, dead
559	1	1	1	1	1	1	0	1	Dead	Euthanized
561	1	1	1	0	1	1	1	1	Dead	Petechiae on legs & breast, dead
563	0	0	1	0	1	1	0	1	Dead	
564	0	0	1	1	1	0	0	1	Dead	Black comb, blotchy hocks, euthanized
565	0	1	1	0	0	1	0	1	Alive	Intestine - tumors
567	0	0	1	0	0	1	0	1	Dead	Euthanized
575	1	1	1	0	1	1	0	1	Dead	
577	1	1	1	0	1	1	0	1	Alive	Sick
580	1	0	1	1	1	1	0	1	Alive	
583	1	1	1	0	0	1	0	1	Dead	Blk comb/euthanized
585	1	0	1	0	1	1	0	1	Alive	Sick. Intestine - tumor
589	1	1	1	0	0	0	0	1	Dead	Petechiae on legs, wings, breast
590	1	1	0	0	0	1	0	1	Dead	Petechiae on breast & wings

Result: "0" indicates no lesions of Marek's disease
"1" indicates lesions of Marek's disease were observed

Group 3: Individual Animal Data

Wing Tag No.	Heart	Liver	Spleen	Gonads	Kidneys	Prov.	Paralysis	Result	End of Study Status	Comments
500	0	0	0	0	0	0	0	0	Alive	
501	0	0	0	0	0	0	0	0	Alive	
503	0	0	0	0	0	0	0	0	Alive	
510	0	0	0	0	0	0	0	0	Alive	
513	0	0	0	0	0	0	0	0	Alive	
517	0	0	0	0	0	0	0	0	Alive	
522	0	0	0	0	0	0	0	0	Alive	
523	0	0	0	0	0	0	0	0	Alive	
526	0	0	0	0	0	0	0	0	Alive	
527	0	0	0	0	0	0	0	0	Alive	
528	0	0	0	0	0	0	0	0	Alive	
529	0	0	0	0	0	0	0	0	Alive	
533	0	0	0	0	0	0	0	0	Alive	
539	0	0	0	0	0	0	0	0	Alive	
545	0	0	0	0	0	0	0	0	Alive	
548	0	0	0	0	0	0	0	0	Alive	
551	0	0	0	0	0	0	0	0	Alive	
552	0	0	0	0	0	0	0	0	Alive	
562	0	0	0	0	0	0	0	0	Alive	
566	0	0	0	0	0	0	0	0	Alive	
568	0	0	0	0	0	0	0	0	Alive	
569	0	0	0	0	0	0	0	0	Alive	
570	0	0	0	0	0	0	0	0	Alive	
572	0	0	0	0	0	0	0	0	Alive	
587	0	0	0	0	0	0	0	0	Alive	

Result: “0” indicates no lesions of Marek’s disease
“1” indicates lesions of Marek’s disease were observed

Study Type	Efficacy
Pertaining to	Newcastle Disease Virus
Study Purpose	Evaluate the efficacy against Newcastle Disease Virus (NDV)
Product Administration	One dose administered *in ovo* at 18 days embryonation
Study Animals	Group 6: 33 embryos, low dose vaccine Group 9: 13 embryos, diluent inoculated
Challenge Description	All birds challenged with Newcastle virus at four weeks post-vaccination
Interval observed after challenge	Observed for clinical signs for 14 days post-challenge
Results	Vaccinates and controls were evaluated for clinical signs and/or death caused by NDV. Birds affected by NDV: Group 6: 1/33 Group 9: 13/13 Requirements per 9 CFR 113.329(c)(3) were met. Raw data attached
USDA Approval Date	October 31, 2016

Table 1: Post-Challenge Bird Observation Record, vaccine

Treatment Group	Wing Tag No.	Isolation Unit No.	Status at end of study	Result
6	1290	17	alive	0
	1298	19	alive	0
	1299	17	dead	1
	1304	17	alive	0
	1311	17	alive	0
	1313	17	alive	0
	1328	19	alive	0
	1330	19	alive	0
	1334	17	alive	0
	1342	19	alive	0
	1349	17	alive	0
	1350	17	alive	0
	1362	19	alive	0
	1385	17	alive	0
	1394	17	alive	0
	1408	17	alive	0
	1409	17	alive	0
	1412	19	alive	0
	1447	19	alive	0
	1451	19	alive	0
	1469	19	alive	0
	1472	19	alive	0
	1473	19	alive	0
	1476	19	alive	0
	1486	19	alive	0
	1497	19	alive	0
	1512	17	alive	0
	1522	19	alive	0
	1532	17	alive	0
	1536	17	alive	0
	1540	17	alive	0
	1541	19	alive	0
	1543	19	alive	0

Result: "0" indicates not affected by Newcastle Disease
"1" indicates affected by Newcastle Disease

Table 2: Post-Challenge Bird Observation Record, diluent

Treatment Group	Wing Tag No.	Isolation Unit No.	Status at end of study	Result
9	1278	19	dead	1
	1314	20	dead	1
	1322	17	dead	1
	1355	17	dead	1
	1360	21	dead	1
	1382	20	dead	1
	1407	17	dead	1
	1413	16	dead	1
	1426	19	dead	1
	1446	16	dead	1
	1467	18	dead	1
	1496	21	dead	1
	1531	18	dead	1

Scoring: "0" indicates not affected by Newcastle Disease
"1" indicates affected by Newcastle Disease

Study Type	Efficacy
Pertaining to	Newcastle Disease Virus
Study Purpose	Evaluate the efficacy against Newcastle Disease Virus (NDV)
Product Administration	One dose administered by the subcutaneous route
Study Animals	Day-old chicks divided into two groups: Group 6, 31 chicks, low dose vaccine Group 9, 13 chicks, diluent inoculated
Challenge Description	Challenged with Newcastle virus at four weeks postvaccination
Interval observed after challenge	Observed for clinical signs for 14 days postchallenge
Results	Vaccinates and controls were evaluated for clinical signs and/or death caused by NDV. Birds affected by NDV: Group 6: 0/31 Group 9: 13/13 Requirements per 9 CFR 113.329(c)(3) were met. Raw data attached
USDA Approval Date	October 26, 2016

Table 1: Post-challenge Bird Observation, vaccine

Treatment Group	Wing Tag No.	Isolation Unit No.	Status at end of study	Result
6	25	17	alive	0
	30	17	alive	0
	32	17	alive	0
	33	17	alive	0
	38	17	alive	0
	42	17	alive	0
	50	17	alive	0
	56	17	alive	0
	77	17	alive	0
	81	17	alive	0
	90	17	alive	0
	92	17	alive	0
	94	17	alive	0
	101	17	alive	0
	104	17	alive	0
	114	17	alive	0
	123	21	alive	0
	130	21	alive	0
	168	21	alive	0
	171	21	alive	0
	203	21	alive	0
	211	21	alive	0
	213	21	alive	0
	222	21	alive	0
	227	21	alive	0
	242	21	alive	0
	244	21	alive	0
	248	21	alive	0
	255	21	alive	0
	264	21	alive	0
	273=800	21	alive	0

Result: "0" indicates not affected by Newcastle Disease
"1" indicates affected by Newcastle Disease

Table 4: Post-challenge Bird Observation, diluent

Treatment Group	Wing Tag No.	Isolation Unit No.	Status at end of study	Result
9	82	17	dead	1
	85	17	dead	1
	89	17	dead	1
	98	21	dead	1
	118	21	dead	1
	156	18	dead	1
	160	18	dead	1
	163	19	dead	1
	188	19	dead	1
	190	20	dead	1
	221	20	dead	1
	250	16	dead	1
	271	16	dead	1

Result: "0" indicates not affected by Newcastle Disease
"1" indicates affected by Newcastle Disease

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety of product under typical field conditions
Product Administration	One dose was administered *in ovo* to 18-19 day old chicken embryos at Site 1 and Site 2. One dose was administered subcutaneously to day-old chickens at Site 3 and Site 4. At each site, one group received the test vaccine and one group received vaccinations according to site standard practices.
Study Animals	A total of 132,300 test chicks in 4 states; 83,900 embryos and 48,400 day-old chicks.
Challenge Description	NA
Interval observed after vaccination	Chicks were observed for daily mortality 21 days after vaccination.
Results	

Site Identifier	Route of Administration	Treatment Group	Total Placed	21 Day Mortality	% Mortality	% Hatachability	Condemnation Rates
01	In Ovo	Control Group	26500	390	1.5	90.28%	0.13%
01	In Ovo	Test Group	26500	323	1.2	89.62%	0.10%
02	In Ovo	Control Group	57400	1405	2.4	88.98%	0.34%
02	In Ovo	Test Group	57400	1292	2.3	88.98%	0.34%
03	Subcutaneous	Control Group	24400	411	1.7	NA	0.12%
03	Subcutaneous	Test Group	24400	328	1.3	NA	0.10%
04	Subcutaneous	Control Group	23800	513	2.2	NA	0.03%
04	Subcutaneous	Test Group	24000	368	1.5	NA	0.03%

NA = Not Applicable

No adverse reactions attributable to vaccination with the test article were reported.

USDA Approval Date	October 19, 2018