Summary of Studies Supporting USDA Product Licensure

Establishment Name	Ceva Animal Health, LLC
USDA Vet Biologics Establishment Number	368
Product Code	1A88.R2
True Name	Bursal Disease-Marek's Disease Vaccine, Serotypes 2 & 3, Live Virus, Live Marek's Disease Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Biomune Company VECTORMUNE HVT IBD & SB1 - No distributor specified
Date of Compilation Summary	July 14, 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	Infectious Bursal Disease Virus (IBDV) Standard and Variant types
Study Purpose	To demonstrate efficacy against IBDV Standard and Variant types
Product Administration	Subcutaneous
Study Animals	
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 31, 2002

Study Type	Efficacy
Pertaining to	Infectious Bursal Disease Virus
Study Purpose	To demonstrate efficacy against IBDV Delaware Variant E and IBDV Standard strains
Product Administration	*In ovo*
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	May 20, 2003

Study Type	Efficacy
Pertaining to	Marek's Disease Virus
Study Purpose	To demonstrate effectiveness against Marek's Disease Virus (MDV) RB1/B
Product Administration	Chickens were vaccinated at day of age via the subcutaneous (SQ) route
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	January 31, 2002

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Marek’s Disease Virus (MDV)</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate effectiveness against Marek’s Disease Virus</td></tr>
<tr><td>Product Administration</td><td>One dose administered via the subcutaneous (SQ) route</td></tr>
<tr><td>Study Animals</td><td>SPF chickens; 45 vaccinates vaccinated at day of age; 45 vaccinates vaccinated with a commercially available HVT vaccine at day of age; 45 non-vaccinated, challenged positive controls; 45 non-vaccinated, non-challenged negative controls</td></tr>
<tr><td>Challenge Description</td><td>MDV RB1/B strain at five days of age</td></tr>
<tr><td>Interval observed after challenge</td><td>Daily observation for 44 days post challenge</td></tr>
<tr><td>Results</td><td>A chicken was considered affected by the challenge (positive) if grossly observable lesions of Marek’s disease virus were present. The lesions included, but were not limited to:

1. Enlargement of sciatic nerves
2. Tumors in the kidneys, spleen, liver, heart, gonad, skin or eyes

<table>
<tr><td>Treatment Group</td><td>Number Affected</td><td>Percentage Affected</td></tr>
<tr><td>SQ vaccinates</td><td>9/45</td><td>20%</td></tr>
<tr><td>SQ vaccinates-commercial HVT vaccine, serotype 3</td><td>12/45</td><td>27%</td></tr>
<tr><td>RB1/B challenged positive controls</td><td>40/45</td><td>89%</td></tr>
<tr><td>Negative controls</td><td>0/45</td><td>0%</td></tr>
</table>

The study fulfilled 9CFR 113.330(c).

Raw data are shown on the attached page.</td></tr>
<tr><td>USDA Approval Date</td><td>May 9, 2014</td></tr>
</table>

Vaccinate ID	Lesions[1]	Commercial Vaccinate ID	Lesions	Positive Control ID	Lesions	Negative Control ID	Lesions
821	Pos[2]	828	Neg	827	Pos	822	Neg
823	Neg[3]	830	Neg	829	Neg	825	Neg
824	Pos	837	Pos	832	Pos	826	Neg
831	Neg	841	Neg	833	Pos	834	Neg
838	Neg	846	Neg	835	Pos	843	Neg
842	Neg	847	Pos	836	Pos	845	Neg
844	Neg	852	Pos	839	Pos	849	Neg
848	Neg	859	Pos	840	Pos	850	Neg
851	Neg	861	Neg	853	Pos	854	Neg
865	Neg	863	Pos	855	Pos	856	Neg
867	Pos	864	Pos	857	Neg	860	Neg
873	Neg	872	Neg	858	Pos	868	Neg
879	Neg	876	Neg	862	Pos	869	Neg
881	Neg	883	Pos	866	Pos	870	Neg
882	Neg	886	Pos	875	Pos	871	Neg
887	Neg	894	Pos	877	Pos	874	Neg
888	Neg	897	Pos	878	Pos	880	Neg
892	Neg	898	Neg	884	Pos	891	Neg
893	Neg	904	Neg	885	Pos	896	Neg
900	Neg	905	Neg	889	Neg	899	Neg
901	Neg	906	Neg	890	Pos	908	Neg
902	Pos	911	Neg	895	Pos	913	Neg
907	Neg	915	Neg	903	Pos	919	Neg
916	Pos	929	Neg	909	Pos	924	Neg
917	Neg	931	Neg	910	Pos	925	Neg
921	Neg	934	Pos	912	Pos	927	Neg
922	Neg	935	Neg	914	Pos	928	Neg
923	Neg	936	Neg	918	Pos	939	Neg
930	Neg	943	Neg	920	Neg	941	Neg
932	Neg	945	Neg	926	Pos	948	Neg
937	Pos	946	Neg	933	Pos	950	Neg
938	Neg	949	Neg	940	Pos	952	Neg
944	Neg	951	Neg	942	Pos	953	Neg
947	Neg	958	Neg	955	Pos	954	Neg
959	Pos	961	Pos	956	Pos	964	Neg
965	Neg	962	Neg	957	Pos	967	Neg
966	Neg	969	Neg	960	Pos	968	Neg
973	Neg	971	Neg	963	Pos	970	Neg
974	Neg	976	Neg	980	Pos	972	Neg
975	Neg	978	Neg	982	Pos	977	Neg
985	Pos	984	Neg	983	Pos	979	Neg
986	Neg	988	Neg	991	Neg	981	Neg

987	Neg	989	Neg	992	Pos	995	Neg
993	Pos	990	Neg	997	Pos	999	Neg
996	Neg	994	Neg	998	Pos	1000	Neg

[1]Grossly observable lesions caused by Marek's disease
[2]Pos=positive
[3]Neg=negative

Study Type	Efficacy
Pertaining to	Marek's Disease Virus (MDV)
Study Purpose	To demonstrate efficacy against Marek's Disease Virus (MDV) RB1/B
Product Administration	Chickens were vaccinated at 18 days of embryonation via the *in ovo* route
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	May 20, 2003

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<tr><td>Study Purpose</td><td>To demonstrate effectiveness against Marek’s Disease Virus</td></tr>
<tr><td>Product Administration</td><td>One dose administered via the in ovo route</td></tr>
<tr><td>Study Animals</td><td>SPF chickens; 45 vaccinates vaccinated via in ovo route at 18 days of incubation; 45 vaccinates vaccinated with a commercially available HVT vaccine via SQ route at day of age; 45 placebo-vaccinated, challenged positive controls via the in ovo route at 18 days of incubation; 45 placebo-vaccinated, non-challenged negative controls via the SQ route at day of age</td></tr>
<tr><td>Challenge Description</td><td>MDV RB1/B strain at five days of age</td></tr>
<tr><td>Interval observed after challenge</td><td>Daily observation for 44 days post challenge</td></tr>
<tr><td>Results</td><td>A chicken was considered affected by the challenge (positive) if grossly observable lesions of Marek′s disease virus were present. The lesions included, but were not limited to:

1. Enlargement of sciatic nerves
2. Tumors in the kidneys, spleen, liver, heart, gonad, skin or eyes

<table>
<tr><td>Treatment Group</td><td>Route of Administration</td><td>Number Affected</td><td>Percentage Affected</td></tr>
<tr><td>Vaccinates</td><td>In ovo</td><td>5/45</td><td>11%</td></tr>
<tr><td>Vaccinates-commercial HVT vaccine, serotype 3</td><td>SQ</td><td>15/45</td><td>33%</td></tr>
<tr><td>RB1/B challenged positive controls</td><td>In ovo</td><td>41/45</td><td>91%</td></tr>
<tr><td>Negative controls</td><td>SQ</td><td>0/45</td><td>0%</td></tr>
</table>

The study fulfilled 9CFR 113.330(c).

Raw data are shown on the attached page.</td></tr>
<tr><td>USDA Approval Date</td><td>May 8, 2014</td></tr>
</table>

Vaccinate ID	Lesions[1]	Commercial Vaccinate ID	Lesions	Positive Control ID	Lesions	Negative Control ID	Clinical Signs
433	Neg[2]	440	Neg	445	Pos	435	Neg
434	Neg	444	Neg	447	Pos	442	Neg
436	Neg	460	Pos	448	Pos	443	Neg
437	Neg	468	Neg	456	Pos	452	Neg
438	Neg	469	Neg	457	Pos	455	Neg
439	Neg	476	Pos	458	Neg	459	Neg
441	Pos[3]	481	Neg	464	Neg	462	Neg
450	Pos	483	Neg	466	Pos	465	Neg
451	Neg	496	Neg	471	Pos	473	Neg
453	Pos	497	Pos	479	Pos	474	Neg
454	Neg	499	Neg	482	Pos	475	Neg
461	Neg	500	Neg	492	Pos	478	Neg
467	Neg	501	Neg	493	Pos	480	Neg
472	Neg	503	Pos	495	Pos	485	Neg
477	Neg	506	Neg	498	Pos	487	Neg
484	Pos	508	Pos	504	Pos	507	Neg
488	Neg	510	Pos	509	Pos	511	Neg
489	Neg	515	Neg	513	Pos	518	Neg
490	Neg	520	Neg	514	Pos	524	Neg
491	Neg	521	Neg	516	Pos	528	Neg
502	Neg	535	Neg	517	Pos	534	Neg
505	Neg	542	Neg	522	Pos	540	Neg
512	Neg	543	Neg	531	Pos	545	Neg
519	Neg	547	Pos	532	Pos	548	Neg
523	Neg	549	Neg	533	Pos	552	Neg
525	Neg	550	Neg	538	Pos	558	Neg
526	Neg	554	Neg	541	Pos	562	Neg
527	Neg	559	Pos	557	Pos	563	Neg
529	Neg	560	Neg	561	Pos	567	Neg
536	Neg	565	Pos	564	Pos	571	Neg
539	Pos	577	Neg	569	Pos	572	Neg
546	Neg	585	Neg	570	Pos	576	Neg
551	Neg	586	Pos	574	Neg	582	Neg
553	Neg	587	Neg	575	Pos	591	Neg
555	Neg	592	Pos	580	Neg	595	Neg
556	Neg	598	Pos	581	Pos	596	Neg
566	Neg	606	Neg	583	Pos	599	Neg
578	Neg	608	Neg	588	Pos	601	Neg
579	Neg	611	Pos	590	Pos	603	Neg
584	Neg	612	Neg	594	Pos	604	Neg
589	Neg	614	Pos	600	Pos	605	Neg
593	Neg	615	Neg	602	Pos	616	Neg

597	Neg	617	Pos	607	Pos	621	Neg
619	Neg	620	Neg	609	Pos	623	Neg
622	Neg	624	Neg	613	Pos	625	Neg

[1]Grossly observable lesions caused by Marek's disease
[2]Neg=negative
[3]Pos=positive

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety of product under typical use condition
Product Administration	Chicken eggs at 18-19 days of embryonation by *in ovo* administration; day-of-age chickens by subcutaneous administration
Study Animals	
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	October 3, 2006