Summary of Studies Supporting USDA Product Licensure

Establishment Name	Ceva Animal Health, LLC
USDA Vet Biologics Establishment Number	368
Product Code	1A88.R0
True Name	Bursal Disease-Marek's Disease Vaccine, Serotype 3, Live Marek's Disease Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Biomune Company VECTORMUNE HVT IBD - Ceva Animal Health Ltd VECTORMUNE HVT IBD - No distributor specified
Date of Compilation Summary	February 05, 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
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	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	Marek's Disease Virus (MDV) GA strain
Study Purpose	To demonstrate efficacy against MDV GA
Product Administration	1. One dose administered by the *in ovo* route 2. One dose administered by the subcutaneous (SQ) route to day of age chickens
Study Animals	38 SPF chicken embryos (vaccinates) vaccinated at 18 days of incubation 35 SPF chicken embryos (negative controls) mock vaccinated at 18 days of incubation 35 SPF chicks (vaccinates) vaccinated SQ at day of age 35 SPF day of age chicks not vaccinated positive controls
Challenge Description	MDV GA administered at five days of age
Interval observed after challenge	Daily observation for 45 days post challenge; tissues examined at 45 days post challenge
Results	A chicken was considered affected by the challenge (positive) if grossly observable lesions caused by the MDV GA challenge were present. 5/38 *in ovo* vaccinates, 5/35 SQ vaccinates, 29/35 positive controls and 0/35 negative controls were affected by the challenge. 87% of *in ovo* vaccinates were protected against MDV GA and 86% of SQ vaccinates were protected against MDV GA. Raw data are shown on the attached page.
USDA Approval Date	March 16, 2007

In Ovo Vaccinate ID	Marek's Lesions[1]	SQ Vaccinate ID	Marek's Lesions	Positive Control ID	Marek's Lesions
447	K,Sp,H,G	344	G	248	N
711	L,H,G,M	870	K,L,G	640	K,H,G
371	K,H	515	G	1030	K,Sp,G
903	K,Sp,L,G	952	K	152	K,Sp,L,G
962	Sp,L	1052	K,H	276	K,L,H,O
				425	K,L,H,G,O
				119	Sp,L,H,G,N, O
				882	K,Sp,L,H,G
				653	K,Sp,G
				1056	K
				843	Sp,L,H,G
				531	Sp,H,G
				163	H
				555	Sp,G
				931	K,L
				902	K,L
				435	K,Sp,L,G
				696	Sp,L
				206	K
				529	K,G
				910	K,Sp,G
				226	G
				157	K,Sp,L
				682	K
				186	K,Sp,L
				513	K,Sp,L
				497	K
				353	K,Sp,L,H,G
				545	G

[1] Tissue with lesion: K=kidney, Sp=spleen, L=liver, H=heart, G=gonad, N=nerves, Sk=skin, E=eye, M=muscle, O=other, NA=not applicable (death, bird experienced trauma, no lesions present)

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety under field conditions
Product Administration	Commercial chicken embryos at 18 to 19 days of incubation by the *in ovo* route and commercial chicks at day of age by 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	October 3, 2006