



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Biomune Company
USDA Vet Biologics Establishment Number	368
Product Code	1D61.R0
True Name	Avian Encephalomyelitis-Fowl Pox-Mycoplasma Gallisepticum Vaccine, Live Virus, Live Fowl Pox Vector
Tradenname(s) / Distributor or Subsidiary (if different from manufacturer)	VECTORMUNE FP-MG+AE - Axis Agency Services Ltd. VECTORMUNE FP-MG+AE - Biomune Company VECTORMUNE FP-MG+AE - CEVA Animal Health (Thailand) Ltd VECTORMUNE FP-MG+AE - CEVA Salud Animal S.A.C.-Peru VECTORMUNE FP-MG+AE - Ceva Salud Animal S.A. de C.V. (Mexico) VECTORMUNE FP-MG+AE - Ceva Sante Animale VECTORMUNE FP-MG+AE - Ceva Sante Animale (Russia) VECTORMUNE FP-MG+AE - Ceva Saude Animal LTDA VECTORMUNE FP-MG+AE - Dimune S.A. VECTORMUNE FP-MG+AE - No distributor specified VECTORMUNE FP-MG+AE - Rebexa S.A. - Biomune Company
Date of Compilation Summary	September 17, 2019

**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.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Avian Encephalomyelitis
<b>Study Purpose</b>	Demonstrate efficacy Avian Encephalomyelitis
<b>Product Administration</b>	Chickens at 8 weeks of age via the wing web route
<b>Study Animals</b>	Chickens
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	October 26, 2000

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Fowl Pox Virus and Mycoplasma Gallisepticum
<b>Study Purpose</b>	Demonstrate efficacy against disease caused by Fowl Pox Virus and Mycoplasma Gallisepticum
<b>Product Administration</b>	Chickens at 8 weeks of age or older via the wing web route
<b>Study Animals</b>	Chickens
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	October 1, 2001

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	Demonstrate safety of product under typical use conditions
<b>Product Administration</b>	Chickens at 8 weeks of age by the wing web route
<b>Study Animals</b>	Chickens
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	December 18, 2002

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	Demonstrate safety of product under typical use conditions.
<b>Product Administration</b>	Chickens 8 weeks of age by web wing route
<b>Study Animals</b>	Chicken
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	April 2, 2003