



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Ceva Animal Health, LLC
USDA Vet Biologics Establishment Number	368
Product Code	1D51.R0
True Name	Fowl Pox-Mycoplasma Gallisepticum Vaccine, Live Fowl Pox Vector
Tradenname(s) / Distributor or Subsidiary (if different from manufacturer)	<p>Biomune Company            VECTORMUNE FP-MG - Axis Agency Services Ltd.            VECTORMUNE FP-MG - Biomune - Biomune Company            VECTORMUNE FP-MG - Biomune Company            VECTORMUNE FP-MG - CEVA Animal Health (Thailand) Ltd            VECTORMUNE FP-MG - CEVA Animal Health (Thailand) Ltd - Biomune Company            VECTORMUNE FP-MG - CEVA Salud Animal S.A.C.-Peru - Biomune Company            VECTORMUNE FP-MG - CEVA Saude Animal Ltda. (Brazil) - Biomune Company            VECTORMUNE FP-MG - Ceva Polchem Pvt. LTD. (India)            VECTORMUNE FP-MG - Ceva Polchem Pvt. LTD. (India) - Biomune Company            VECTORMUNE FP-MG - Ceva Sante Animale            VECTORMUNE FP-MG - Ceva Sante Animale (Russia)            VECTORMUNE FP-MG - No distributor specified            VECTORMUNE FP-MG - Rehexas S.A. - Biomune Company            VECTORMUNE FP-MG - Vetiplus S.A.</p>
Date of Compilation Summary	August 18, 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.**

<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>	Efficacy
<b>Pertaining to</b>	Fowl Pox Virus and Mycoplasma Gallisepticum
<b>Study Purpose</b>	Establish the duration of immunity of the Fowl Pox Virus and Mycoplasma Gallisepticum at least 12 weeks post-vaccination
<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>	September 26, 2002

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Fowl Pox Virus and Mycoplasma Gallisepticum
<b>Study Purpose</b>	Demonstrate efficacy against disease at 5 weeks post-vaccination caused by Fowl Pox Virus and Mycoplasma Gallisepticum
<b>Product Administration</b>	Turkeys at 4 weeks of age or older via the wing web route
<b>Study Animals</b>	Turkeys
<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 22, 2003

<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>	Turkeys 4 weeks of age by the wing web route
<b>Study Animals</b>	Turkeys
<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>	February 5, 2004

<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