Summary of Studies Supporting USDA Product Licensure

Establishment Name	Ceva Animal Health, LLC
USDA Vet Biologics Establishment Number	368
Product Code	10S1.R0
True Name	Avian Encephalomyelitis-Fowl Pox-Laryngotracheitis Vaccine, Live Virus, Live Fowl Pox Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Biomune Company VECTORMUNE FP-LT+AE - Axis Agency Services Ltd. VECTORMUNE FP-LT+AE - Biomune - Biomune Company VECTORMUNE FP-LT+AE - Biomune Company VECTORMUNE FP-LT+AE - CEVA Animal Health (Pty) Ltd VECTORMUNE FP-LT+AE - CEVA Animal Health (Thailand) Ltd VECTORMUNE FP-LT+AE - Ceva Hayvan Sagligi A.S. - Biomune Company VECTORMUNE FP-LT+AE - Ceva Salud Animal S.A. de C.V. (Mexico) VECTORMUNE FP-LT+AE - Ceva Salud Animal SRL - Biomune Company VECTORMUNE FP-LT+AE - Ceva Sante Animale VECTORMUNE FP-LT+AE - Ceva Saude Animal LTDA - Biomune Company VECTORMUNE FP-LT+AE - MAS Veterinary Services VECTORMUNE FP-LT+AE - No distributor specified
Date of Compilation Summary	July 12, 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	Avian Encephalomyelitis
Study Purpose	Demonstrate efficacy Avian Encephalomyelitis
Product Administration	Chickens at 8 weeks of age via the wing web 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 26, 2000

Study Type	Efficacy
Pertaining to	Fowl Pox Virus, Laryngotracheitis, and Avian Encephalomyelitis
Study Purpose	Demonstrate efficacy against Fowl Pox Virus, Laryngotracheitis, and Avian Encephalomyelitis
Product Administration	
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 26, 2000

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety of product under typical use conditions
Product 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	August 23, 2002