

## **Summary of Studies Supporting USDA Product Licensure**

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	15E2.00
True Name	Fowl Pox-Marek's Disease Vaccine, Serotype 3, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	May 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.

124 15E2.00 Page 1 of 6

Study Type	Efficacy
Pertaining to	Marek's Disease Virus
Study Purpose	Efficacy against Marek's Disease
<b>Product Administration</b>	Subcutaneous at day-of-age
<b>Study Animals</b>	Chickens
<b>Challenge Description</b>	Marek's Disease Virus RB1B
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.
<b>USDA Approval Date</b>	January 26, 1990

124 15E2.00 Page 2 of 6

Study Type	Efficacy
Pertaining to	Marek's Disease
Study Purpose	Demonstrate efficacy against Marek's Disease
<b>Product Administration</b>	Subcutaneously
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.
<b>USDA Approval Date</b>	June 28, 1984

124 15E2.00 Page 3 of 6

Study Type	Efficacy
Pertaining to	Marek's Disease
Study Purpose	Efficacy against Marek's Disease
<b>Product Administration</b>	Subcutaneously (SQ)
Study Animals	Chickens
<b>Challenge Description</b>	
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.
<b>USDA Approval Date</b>	January 17, 1980

124 15E2.00 Page 4 of 6

Study Type	Efficacy
Pertaining to	Fowl pox
Study Purpose	Demonstrate efficacy against Fowl pox
<b>Product Administration</b>	Subcutaneously
Study Animals	Chickens
<b>Challenge Description</b>	
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.
<b>USDA Approval Date</b>	June 28, 1984

124 15E2.00 Page 5 of 6

Study Type	Safety
Pertaining to	ALL
Study Purpose	To evaluate safety under field conditions
<b>Product Administration</b>	Subcutaneously
<b>Study Animals</b>	Chickens
<b>Challenge Description</b>	
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	September 26, 1984

124 15E2.00 Page 6 of 6