Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	16T1.00
True Name	Marek's Disease-Tenosynovitis Vaccine, Serotypes 2 & 3, Live & Modified 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.

Study Type	Efficacy
Pertaining to	Marek's Disease
Study Purpose	Demonstrate efficacy against Marek's disease
Product Administration	Subcutaneously (SQ)
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. Study data, however, are no longer available.
USDA Approval Date	July 30, 1986

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

Study Type	Efficacy
Pertaining to	Marek's Disease
Study Purpose	Efficacy against Marek's disease
Product Administration	Subcutaneously (SQ)
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	March 14, 1985

Study Type	Efficacy
Pertaining to	Marek's Disease
Study Purpose	Demonstrate efficacy against Marek's disease
Product Administration	Subcutaneously (SQ)
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	1991

Study Type	Efficacy
Pertaining to	Marek's Disease
Study Purpose	Efficacy against Marek's Disease
Product Administration	Subcutaneously (SQ)
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	January 17, 1980

Study Type	Efficacy
Pertaining to	Tenosynovitis
Study Purpose	Demonstrate efficacy against tenosynovitis caused by Reovirus
Product Administration	Subcutaneously (SQ)
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	November 7, 1985

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions
Product Administration	Subcutaneously (SQ)
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	August 4, 1992