



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	12C8.43
True Name	Bursal Disease-Marek's Disease Vaccine, Standard & Variant, Serotype 3, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	August 11, 2020

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	Infectious bursal disease virus, standard
Study Purpose	Demonstrate efficacy against infectious bursal disease virus, standard
Product Administration	In ovo
Study Animals	Chicken eggs at 18 days of embryonation
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	May 23, 1994

Study Type	Efficacy
Pertaining to	Infectious bursal disease virus, variant
Study Purpose	Demonstrate efficacy against infectious bursal disease virus, variant
Product Administration	In ovo
Study Animals	Chicken eggs at 18 days of embryonation
Challenge Description	Variant 1084-E CP ₂
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	May 23, 1994

Study Type	Efficacy
Pertaining to	Infectious bursal disease virus, standard
Study Purpose	Demonstrate efficacy against standard infectious bursal disease virus
Product Administration	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.
USDA Approval Date	May 5, 1982

Study Type	Efficacy
Pertaining to	Infectious bursal disease virus, variant
Study Purpose	Demonstrate efficacy against infectious bursal disease virus, variant
Product Administration	Subcutaneous
Study Animals	Chickens
Challenge Description	Variant E
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 30, 1987

Study Type	Efficacy
Pertaining to	Infectious bursal disease virus, variant
Study Purpose	Demonstrate efficacy against variant infectious bursal disease virus
Product Administration	In ovo
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	February 9, 1994

Study Type	Efficacy
Pertaining to	Infectious bursal disease virus, standard
Study Purpose	Demonstrate efficacy against standard infectious bursal disease virus
Product Administration	In ovo
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	February 9, 1994

Study Type	Efficacy
Pertaining to	Marek's Disease Virus
Study Purpose	Efficacy against Marek's Disease
Product Administration	In ovo at 18-19 days of embryonation
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	October 8, 1993

Study Type	Efficacy
Pertaining to	Marek's disease
Study Purpose	Demonstrate efficacy against Marek's disease
Product Administration	In ovo at 18 days of embryonation
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	May 23, 1994

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 virus
Study Purpose	Demonstrate efficacy against Marek's Disease
Product Administration	In ovo
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	February 9, 1994

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	Safety
Pertaining to	ALL
Study Purpose	Demonstrate in ovo safety under typical field conditions
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	May 23, 1994

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions
Product Administration	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.
USDA Approval Date	December 15, 1987