



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	12C8.42
True Name	Bursal Disease-Marek's Disease Vaccine, Standard & Variant, Serotypes 2 & 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.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious bursal disease virus, standard
<b>Study Purpose</b>	Demonstrate efficacy against infectious bursal disease virus, standard
<b>Product Administration</b>	In ovo
<b>Study Animals</b>	Chicken eggs at 18 days of embryonation
<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>	May 23, 1994

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

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious bursal disease virus, standard
<b>Study Purpose</b>	Demonstrate efficacy against standard infectious bursal disease virus
<b>Product Administration</b>	Subcutaneously
<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>	May 5, 1982

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

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

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

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Marek's Disease Virus
<b>Study Purpose</b>	Efficacy against Marek's Disease
<b>Product Administration</b>	In ovo at 18-19 days of embryonation
<b>Study Animals</b>	Chickens
<b>Challenge Description</b>	Marek's Disease Virus RB1B
<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 15, 2002



<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Marek's Disease Virus
<b>Study Purpose</b>	Efficacy against Marek's Disease
<b>Product Administration</b>	In ovo at 18-19 days of embryonation
<b>Study Animals</b>	Chickens
<b>Challenge Description</b>	Marek's Disease Virus RB1B
<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 8, 1993

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Marek's disease
<b>Study Purpose</b>	Demonstrate efficacy against Marek's disease
<b>Product Administration</b>	In ovo at 18 days of embryonation
<b>Study Animals</b>	Chickens
<b>Challenge Description</b>	Marek's Disease Virus RB1B
<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>	May 23, 1994

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Marek's Disease Virus
<b>Study Purpose</b>	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
<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>	January 26, 1990

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Marek's disease virus
<b>Study Purpose</b>	Demonstrate efficacy against Marek's Disease
<b>Product Administration</b>	In ovo
<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>	February 9, 1994

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

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

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	To evaluate safety under field conditions
<b>Product Administration</b>	Subcutaneously
<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. Study data, however, are no longer available.
<b>USDA Approval Date</b>	January 30, 1990

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	Demonstrate in ovo safety under typical field conditions
<b>Product Administration</b>	
<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>	May 23, 1994