



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1A88.R2
True Name	Bursal Disease-Marek's Disease Vaccine, Serotypes 2 & 3, Live Virus, Live Marek's Disease Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Vaxxitek HVT + IBD SB1 - No distributor specified
Date of Compilation Summary	May 22, 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, variant E
<b>Study Purpose</b>	Demonstrate efficacy against bursal disease, variant E
<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>	August 31, 2001

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious bursal disease, variant E
<b>Study Purpose</b>	Demonstrate efficacy against bursal disease, variant E
<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>	November 3, 2004

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious bursal disease, standard
<b>Study Purpose</b>	Demonstrate efficacy against bursal disease, standard
<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>	August 31, 2001

<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>	Very virulent Marek's Disease
<b>Study Purpose</b>	Demonstrate efficacy against very virulent Marek's disease
<b>Product Administration</b>	In ovo
<b>Study Animals</b>	Embryonated chicken eggs
<b>Challenge Description</b>	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>	December 29, 2004

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Very virulent Marek's Disease
<b>Study Purpose</b>	Demonstrate efficacy against very virulent Marek's disease
<b>Product Administration</b>	Subcutaneously
<b>Study Animals</b>	Chickens at one day of age
<b>Challenge Description</b>	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>	December 29, 2004

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious bursal disease, standard
<b>Study Purpose</b>	Demonstrate efficacy against bursal disease, standard
<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>	November 3, 2004



<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	To evaluate safety under field conditions
<b>Product Administration</b>	In ovo and subcutaneously
<b>Study Animals</b>	Embryonated chicken eggs and chickens at one day of age
<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 24, 2006