Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1A88.R3
True Name	Bursal Disease-Marek's Disease Vaccine, Serotype 3, Live Marek's Disease Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Vaxxitek HVT + IBD AF - No distributor specified
Date of Compilation Summary	November 24, 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, variant E
Study Purpose	Demonstrate efficacy against bursal disease, variant E
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	August 31, 2001

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

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

Study Type	Efficacy
Pertaining to	Marek's Disease
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	August 31, 2001

Study Type	Efficacy
Pertaining to	Marek's Disease
Study Purpose	Demonstrate efficacy against Marek's disease
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	November 3, 2004

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

Study Type	Safety
Pertaining to	ALL
Study Purpose	To evaluate safety under field conditions
Product Administration	In ovo and subcutaneously
Study Animals	Embryonated chicken eggs and chickens at one day of age
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 24, 2004