Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1271.0A
True Name	Bursal Disease Vaccine, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	BDA BLEN - Boehringer Ingelheim Animal Health (Thai) Ltd. BDA BLEN - Boehringer Ingelheim Animal Health Argentina S.A. BDA BLEN - Boehringer Ingelheim Animal Health Mexico BDA BLEN - Boehringer Ingelheim Animal Health do Brasil Ltda BDA BLEN - No distributor specified Gallivac BDA - Abdulrehman Algosabi GTC (Saudi Arabia) Gallivac BDA - No distributor specified
Date of Compilation Summary	November 01, 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	Infectious bursal disease
Study Purpose	Demonstrate efficacy against standard infectious bursal 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	December 9, 1993

Study Type	Efficacy
Pertaining to	Infectious bursal disease
Study Purpose	Demonstrate efficacy against standard infectious bursal disease under field conditions
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	October 31, 1996

Study Type	Efficacy
Pertaining to	Infectious bursal disease
Study Purpose	Demonstrate efficacy against standard infectious bursal disease
Product Administration	Subcutaneously
Study Animals	Chickens at 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	July 9, 1993

Study Type	Efficacy
Pertaining to	Infectious bursal disease
Study Purpose	Demonstrate efficacy against infectious bursal disease when Marek's Disease Vaccine, Serotypes 2 & 3 is administered concurrently with Bursal Disease Vaccine, Live Virus
Product Administration	In ovo at 18-19 days of embryonation
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	October 31, 1996

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions
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	October 31, 1996

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	November 3, 1994