



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	12B1.00
True Name	Bursal Disease Vaccine, Standard & Variant, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	May 17, 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 virus, variant
Study Purpose	Demonstrate efficacy against infectious bursal disease virus, variant
Product Administration	Drinking water
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 27, 1993

Study Type	Efficacy
Pertaining to	Infectious bursal disease virus, variant
Study Purpose	Demonstrate efficacy against infectious bursal disease virus, variant
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	April 18, 1995

Study Type	Efficacy
Pertaining to	Infectious bursal disease virus, variant
Study Purpose	Demonstrate efficacy against infectious bursal disease virus, variant
Product Administration	Coarse aerosol spray
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 23, 1989

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	March 14, 1994

Study Type	Efficacy
Pertaining to	Infectious bursal disease virus, standard
Study Purpose	Demonstrate efficacy against standard infectious bursal disease virus
Product Administration	Drinking water
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 19, 1992

Study Type	Efficacy
Pertaining to	Infectious bursal disease virus, standard
Study Purpose	Demonstrate efficacy against standard infectious bursal disease virus
Product Administration	Coarse aerosol spray
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 4, 1984

Study Type	Efficacy
Pertaining to	Infectious bursal disease virus, standard
Study Purpose	Demonstrate efficacy against infectious bursal disease virus, 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	April 18, 1995

Study Type	Efficacy
Pertaining to	Infectious bursal disease virus, standard
Study Purpose	Demonstrate efficacy against infectious bursal disease virus, standard
Product Administration	Drinking water
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 23, 1989

Study Type	Efficacy
Pertaining to	Infectious bursal disease virus, variant
Study Purpose	Demonstrate efficacy against infectious bursal disease virus, variant
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	April 18, 1995

Study Type	Efficacy
Pertaining to	Infectious bursal disease virus, variant
Study Purpose	Demonstrate efficacy against infectious bursal disease virus, variant
Product Administration	Drinking water
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 23, 1989

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions
Product Administration	Subcutaneously
Study Animals	Chickens
Challenge Description	Not applicable
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	April 18, 1995

Study Type	Safety
Pertaining to	ALL
Study Purpose	To evaluate safety under field conditions
Product Administration	Coarse aerosol spray
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. Study data, however, are no longer available.
USDA Approval Date	August 23, 1989

Study Type	Safety
Pertaining to	ALL
Study Purpose	To evaluate safety under field conditions
Product Administration	Drinking water
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. Study data, however, are no longer available.
USDA Approval Date	August 23, 1989