



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1271.13
True Name	Bursal Disease Vaccine, 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 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>	September 9, 1982

<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, 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>	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>	November 23, 1982

<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