



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	12H1.67
True Name	Bursal Disease-Newcastle Disease-Bronchitis Vaccine, B1 Type, B1 Strain, Mass & Conn Types, 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.**

<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>	Coarse aerosol spray
<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>	December 4, 1984

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious standard bursal disease
<b>Study Purpose</b>	Demonstrate efficacy against standard bursal disease
<b>Product Administration</b>	Coarse spray
<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>	December 22, 1987

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious bronchitis of Connecticut type
<b>Study Purpose</b>	Demonstrate efficacy against infectious bronchitis of Connecticut type.
<b>Product Administration</b>	Coarse spray
<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>	December 22, 1987

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious bronchitis of Massachusetts type
<b>Study Purpose</b>	Demonstrate efficacy against infectious bronchitis of Massachusetts type
<b>Product Administration</b>	Coarse spray
<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>	December 22, 1987

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Avian infectious bronchitis virus, Massachusetts type
<b>Study Purpose</b>	Efficacy against avian infectious bronchitis virus, Massachusetts type
<b>Product Administration</b>	Coarse spray
<b>Study Animals</b>	Chickens at 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>	August 31, 1981

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Avian infectious bronchitis virus, Connecticut type
<b>Study Purpose</b>	Demonstrate efficacy against avian infectious bronchitis virus, Connecticut type
<b>Product Administration</b>	Coarse spray
<b>Study Animals</b>	Chickens at 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>	May 4, 1983

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Newcastle Disease
<b>Study Purpose</b>	Demonstrate efficacy against Newcastle Disease
<b>Product Administration</b>	Coarse spray
<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>	December 22, 1987

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Newcastle disease virus
<b>Study Purpose</b>	Demonstrate efficacy against Newcastle disease
<b>Product Administration</b>	Coarse spray
<b>Study Animals</b>	Chickens at 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>	Dec. 11, 1980

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Newcastle disease virus
<b>Study Purpose</b>	Demonstrate efficacy against Newcastle disease
<b>Product Administration</b>	
<b>Study Animals</b>	
<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>	Jan. 11, 1984

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	To evaluate safety under field conditions
<b>Product Administration</b>	Coarse spray
<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>	1987