Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1762.1J
True Name	Newcastle-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.

Study Type	Efficacy
Pertaining to	Avian infectious bronchitis virus, Connecticut type
Study Purpose	Demonstrate efficacy against avian infectious bronchitis virus, Connecticut type
Product Administration	Drinking water administration
Study Animals	Chickens at 14 days 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	January 11, 1984

Study Type	Efficacy
Pertaining to	Avian infectious bronchitis virus, Massachusetts type
Study Purpose	Efficacy against avian infectious bronchitis virus, Massachusetts type
Product Administration	Coarse spray
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	August 31, 1981

Study Type	Efficacy
Pertaining to	Avian infectious bronchitis virus, Connecticut type
Study Purpose	Demonstrate efficacy against avian infectious bronchitis virus, Connecticut type
Product Administration	Coarse spray
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	May 4, 1983

Study Type	Efficacy
Pertaining to	Avian infectious bronchitis virus, Massachusetts type
Study Purpose	Demonstrate efficacy against avian infectious bronchitis, Massachusetts type
Product Administration	Drinking water administration
Study Animals	Chickens at 14 days 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	March 2, 1984

Study Type	Efficacy
Pertaining to	Newcastle disease virus
Study Purpose	Demonstrate efficacy against Newcastle disease
Product Administration	Coarse spray
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	Dec. 11, 1980

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

Study Type	Safety
Pertaining to	ALL
Study Purpose	To evaluate safety under field conditions
Product Administration	Coarse spray at day-of-age
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	1981

Study Type	Safety
Pertaining to	ALL
Study Purpose	To evaluate safety under field conditions
Product Administration	Drinking water administration
Study Animals	Chickens 10-14 days 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	1981