Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	12P5.40
True Name	Bursal Disease-Newcastle Disease-Reovirus Vaccine, Standard & Variant, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Bursa Guard N-R - No distributor specified
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, standard and variant E
Study Purpose	Demonstrate efficacy against infectious bursal disease, standard and variant E
Product Administration	Subcutaneously (SQ)
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 4, 1995

Study Type	Efficacy
Pertaining to	Infectious bursal disease, standard and variant E
Study Purpose	Demonstrate efficacy in stimulating passive immunity in offspring of birds vaccinated against infectious bursal disease, standard and variant E
Product Administration	Subcutaneously (SQ)
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 1, 1991

Study Type	Efficacy
Pertaining to	Infectious bursal disease, standard and variant E
Study Purpose	Demonstrate efficacy in stimulating passive immunity in offspring of birds vaccinated against infectious bursal disease, standard and variant E
Product Administration	Intramuscularly (IM)
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 27, 1992

Study Type	Efficacy
Pertaining to	Infectious bursal disease, standard and variant E
Study Purpose	Demonstrate efficacy against bursal disease, standard and variant E
Product Administration	Intramuscularly (IM)
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 21, 2005

Study Type	Efficacy
Pertaining to	Newcastle disease
Study Purpose	Demonstrate efficacy against Newcastle disease
Product Administration	Intramuscularly (IM)
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 21, 2005

Study Type	Efficacy
Pertaining to	Newcastle disease
Study Purpose	Demonstrate efficacy against Newcastle disease
Product Administration	Subcutaneously (SQ)
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 22, 1993

Study Type	Efficacy
Pertaining to	Avian reovirus
Study Purpose	Demonstrate efficacy in stimulating passive immunity in offspring of birds vaccinated against reovirus
Product Administration	Intramuscularly (IM)
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 21, 2005

Study Type	Efficacy
Pertaining to	Avian reovirus
Study Purpose	Demonstrate efficacy in stimulating passive immunity in offspring of birds vaccinated against reovirus
Product Administration	Subcutaneously (SQ)
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 22, 1993

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions
Product Administration	Intramuscularly (IM)
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	February 14, 2005

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions
Product Administration	Subcutaneously (SQ)
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 12, 1994