Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	46J9.R1
True Name	Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Live Canarypox Vector, Leptospira Canicola-Icterohaemorrhagiae Bacterin
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	Canine adenovirus type 2 (CAV-2)
Study Purpose	Demonstrate efficacy against canine adenovirus type 1 (canine hepatitis)
Product Administration	Intramuscularly (IM) and subcutaneously (SQ)
Study Animals	Dogs
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	1987

Study Type	Efficacy
Pertaining to	Canine adenovirus type 2 (CAV-2)
Study Purpose	Demonstrate efficacy against canine adenovirus type 2 (canine respiratory disease complex)
Product Administration	Intramuscularly (IM) and subcutaneously (SQ)
Study Animals	Dogs
Challenge Description	
Interval observed after challenge	
Results	Study results applicable to subcutaneous (SQ) route of administration. 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	July 14, 1989

Study Type	Efficacy
Pertaining to	Canine corona virus
Study Purpose	Demonstrate efficacy against canine corona virus
Product Administration	Intramuscularly (IM) and subcutaneously (SQ)
Study Animals	Dogs
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 5, 2000

Study Type	Efficacy
Pertaining to	*Leptospira canicola*
Study Purpose	Demonstrate efficacy against *L. canicola*
Product Administration	Intramuscularly (IM) and subcutaneously (SQ)
Study Animals	Dogs
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	December 4, 1989

Study Type	Efficacy
Pertaining to	*Leptospira icterohaemorrhagiae*
Study Purpose	Demonstrate efficacy against *L. icterohaemorrhagiae*
Product Administration	Intramuscularly (IM) and subcutaneously (SQ)
Study Animals	Dogs
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	December 4, 1989

Study Type	Efficacy
Pertaining to	Canine parainfluenza virus
Study Purpose	Demonstrate efficacy against canine parainfluenza virus
Product Administration	Intramuscularly (IM) and subcutaneously (SQ)
Study Animals	Dogs
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 27, 1998

Study Type	Efficacy
Pertaining to	Canine distemper virus
Study Purpose	Demonstrate efficacy against canine distemper virus
Product Administration	Intramuscularly (IM) and subcutaneously (SQ)
Study Animals	Dogs
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 6, 1995

Study Type	Efficacy
Pertaining to	Canine parvovirus
Study Purpose	Demonstrate efficacy against canine parvovirus
Product Administration	Intramuscularly (IM) and Subcutaneously (SQ)
Study Animals	Dogs
Challenge Description	
Interval observed after challenge	
Results	Study results applicable to intramuscular (IM) route of administration. 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 12, 1994

Study Type	Safety
Pertaining to	Canine Adenovirus Type-2 (CAV-2)
Study Purpose	Development of corneal opacity is not associated with the use of this product
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data are not available.

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions
Product Administration	Intramuscularly (IM) and subcutaneously (SQ)
Study Animals	Dogs
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 25, 1997