



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	13C1.20
True Name	Canine Distemper-Adenovirus Type 2-Parainfluenza Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	July 16, 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 (CAV)
Study Purpose	Demonstration of efficacy against CAV Type 1 by CAV Type 2
Product Administration	
Study Animals	Canine
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	September 14, 2006

Study Type	Efficacy
Pertaining to	Canine adenovirus (CAV)
Study Purpose	Demonstration of efficacy against CAV Type 2 by CAV Type 2
Product Administration	
Study Animals	Canine
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	September 5, 2006

Study Type	Efficacy
Pertaining to	Canine parainfluenza (CPI)
Study Purpose	Demonstration of efficacy against CPI
Product Administration	
Study Animals	Canine
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 26, 1990

Study Type	Efficacy
Pertaining to	Canine distemper virus (CDV)
Study Purpose	Demonstration of efficacy against CDV
Product Administration	Intramuscular
Study Animals	Canine
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 12, 1975

Study Type	Efficacy
Pertaining to	Canine distemper virus (CDV)
Study Purpose	Demonstration of efficacy against CDV
Product Administration	Subcutaneous
Study Animals	Canine
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	June 3, 1980

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 fractions
Study Purpose	To demonstrate safety under field conditions
Product Administration	
Study Animals	Canine
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 3, 2007