



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1331.R1
True Name	Canine Distemper-Adenovirus Type 2-Parvovirus Vaccine, Modified Live Virus, Canarypox Vector
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>	Canine adenovirus type 2 (CAV-2)
<b>Study Purpose</b>	Demonstrate efficacy against canine adenovirus type 1 (canine hepatitis)
<b>Product Administration</b>	Intramuscularly (IM) and subcutaneously (SQ)
<b>Study Animals</b>	Dogs
<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>	1987

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

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

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

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

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