



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Merial, Inc.
USDA Vet Biologics Establishment Number	298
Product Code	18M1.22
True Name	Parvovirus Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Recombitek Canine Parvo - Merial Canada, Inc. Recombitek Canine Parvo - Merial Mexico S.A. DE C.V.
Date of Compilation Summary	September 18, 2018

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 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	<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>
USDA Approval Date	April 12, 1994

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

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions
Product Administration	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 23, 1996