



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	44C9.20
True Name	Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Haemophilus Somnus Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Resvac 4/Somubac - No distributor specified
Date of Compilation Summary	October 25, 2022

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	Bovine Viral Diarrhea Virus, type 1 (BVDV 1)
Study Purpose	Demonstrate efficacy against respiratory disease caused by BVDV 1
Product Administration	
Study Animals	Bovine
Challenge Description	BVDV 1 virus (non-cytopathic type 1b strain New York-1)
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	09/06/1984

Study Type	Efficacy
Pertaining to	Herpes Virus, Bovine [Infectious Bovine Rhinotracheitis (IBR) virus]
Study Purpose	Demonstrate efficacy against disease caused by IBR virus
Product Administration	
Study Animals	Bovine
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	01/19/1984

Study Type	Efficacy
Pertaining to	<i>Haemophilus somnus</i>
Study Purpose	Demonstrate effectiveness against <i>Haemophilus somnus</i>
Product Administration	
Study Animals	Bovine
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 25, 1980

Study Type	Efficacy
Pertaining to	Bovine Parainfluenza type 3 Virus (PI ₃)
Study Purpose	Demonstrate efficacy against respiratory disease caused by PI ₃
Product Administration	
Study Animals	Bovine
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	08/01/1984

Study Type	Efficacy
Pertaining to	Bovine Respiratory Syncytial Virus (BRSV)
Study Purpose	Demonstrate efficacy against respiratory disease caused by BRSV
Product Administration	
Study Animals	Bovine
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	04/12/1989

Study Type	Safety
Pertaining to	All fractions
Study Purpose	Demonstrate safety under field conditions
Product Administration	
Study Animals	Bovine
Challenge Description	NA
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	5/22/1990