Summary of Studies Supporting USDA Product Licensure

Establishment Name	NovaVive USA Inc.
USDA Vet Biologics Establishment Number	289
Product Code	9300.01
True Name	Mycobacterium Cell Wall Fraction Immunostimulant
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Equimune - No distributor specified Equimune - NovaVive Pty Ltd Settle - Agilis Vet LImited Settle - No distributor specified Settle - NovaVive Pty Ltd Settle - SVS Veterinary Supplies Ltd.
Date of Compilation Summary	June 08, 2023

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	Equine Respiratory Disease Complex (ERDC)
Study Purpose	To demonstrate efficacy as an immunotherapeutic for the treatment of ERDC.
Product Administration	Intravenously
Study Animals	Equine
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	June 5, 1990

Study Type	Efficacy
Pertaining to	*Streptococcus zooepidemicus*
Study Purpose	To demonstrate efficacy as an immunotherapeutic for the treatment of equine endometritis due to *Streptococcus zooepidemicus*
Product Administration	Intravenously or Intrauterine
Study Animals	Equine
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	October 14, 2004

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety of product under typical field conditions.
Product Administration	Intravenously
Study Animals	Equine
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	June 5, 1990

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety of product under typical field conditions.
Product Administration	Intravenously and Intrauterine.
Study Animals	Equine
Challenge Description	NA
Interval observed after challenge	
Results	Scientific data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission.
USDA Approval Date	October 14, 2004