



Summary of Studies Supporting USDA Product Licensure

Establishment Name	NovaVive USA Inc.
USDA Vet Biologics Establishment Number	289
Product Code	9300.02
True Name	Mycobacterium Cell Wall Fraction Immunostimulant
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Alpha-CD - No distributor specified Amplimmune - Agilis Vet Limited Amplimmune - No distributor specified
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	<i>E. coli</i> K99
Study Purpose	To demonstrate efficacy for the immunotherapeutic treatment in 1-5 day old calves.
Product Administration	Intravenously
Study Animals	Bovine
Challenge Description	<i>E. coli</i> K99
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 16, 1993

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under field conditions
Product Administration	Intravenously
Study Animals	Bovine calves
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	December 14, 1995