Summary of Studies Supporting USDA Product Licensure

Establishment Name	NovaVive USA Inc.
USDA Vet Biologics Establishment Number	289
Product Code	9300.00
True Name	Mycobacterium Cell Wall Fraction Immunostimulant
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Immunocidin - No distributor specified Immunocidin - NovaVive Inc.
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 Sarcoid Tumors in Horses
Study Purpose	For immunotherapeutic treatment of tumors.
Product Administration	Intratumoral
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	July 23, 1981

Study Type	Efficacy
Pertaining to	Mixed Mammary Tumor & Canine Adenocarcinoma in Dogs
Study Purpose	For immunotherapeutic treatment of tumors.
Product Administration	Intratumoral
Study Animals	Canine
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	1983

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety of product under typical use conditions.
Product Administration	Intratumoral
Study Animals	Canine
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	1983

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety of product under typical use conditions.
Product Administration	Intratumoral
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	July 23, 1981