Summary of Studies Supporting USDA Product Licensure

Establishment Name	Neogen Corporation
USDA Vet Biologics Establishment Number	302
Product Code	9350.00
True Name	Propionibacterium Acnes Immunostimulant
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	EqStim - No distributor specified ImmunoRegulin - No distributor specified
Date of Compilation Summary	June 29, 2021

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	Propionibacterium Acnes
Study Purpose	To demonstrate efficacy against equine respiratory disease complex as an adjunct to conventional therapy
Product Administration	Intravenous
Study Animals	Equine
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	June 8, 1988

Study Type	Efficacy
Pertaining to	Propionibacterium Acnes
Study Purpose	To demonstrate efficacy against canine pyoderma as an adjunct to antibiotic therapy
Product Administration	Intravenous
Study Animals	Canine
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	March 10, 1987

Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety of product under typical field conditions
Product Administration	
Study Animals	Equine
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. Study data, however, are no longer available.
USDA Approval Date	March 16, 1987

Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety of product under typical field conditions
Product Administration	
Study Animals	Canine
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. Study data, however, are no longer available.
USDA Approval Date	March 16, 1987