Summary of Studies Supporting USDA Product Licensure

Establishment Name	Pharmgate Biologics, Inc.
USDA Vet Biologics Establishment Number	329
Product Code	2775.01
True Name	Mycoplasma Hyopneumoniae Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Bayovac MycoGuard-1 - Bayer Thai Co., Ltd. Bayovac MycoGuard-1 - Bayer Thai Co., Ltd. - Pharmgate Biologics Inc. Bayovac MycoGuard-1 - Bayer Vietnam Ltd. - Pharmgate Biologics Inc. Bayovac MycoGuard-1 - Pharmgate Biologics Inc. MycoGard 1 Time - No distributor specified MycoGard 1 Time - Pharmgate Biologics Inc. MycoGard One Time - Pharmgate Biologics Inc. Pharmgate Biologics Inc.
Date of Compilation Summary	June 04, 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	*Mycoplasma hyopneumoniae*
Study Purpose	Demonstrate effectiveness against *Mycoplasma hyopneumoniae*
Product Administration	
Study Animals	Swine
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	July 11, 2001

Study Type	Efficacy
Pertaining to	*Mycoplasma hyopneumoniae*
Study Purpose	Demonstrate effectiveness against *Mycoplasma hyopneumoniae* 164 days after vaccination
Product Administration	
Study Animals	
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	July 11, 2001

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety of product under typical use conditions.
Product Administration	Intramuscular
Study Animals	Swine
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 17, 2001