

Summary of Studies Supporting USDA Product Licensure

Establishment Name	American Animal Health, Inc.
USDA Vet Biologics Establishment Number	315
Product Code	7935.01
True Name	Mannheimia Haemolytica-Pasteurella Multocida Bacterin- Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Leukotox M-1 - No distributor specified Pulmo-Guard PHM-1 - Agri Laboratories, Ltd. Pulmo-Guard PHM-1 - Huvepharma, Inc
Date of Compilation Summary	November 08, 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.

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Study Type	Efficacy
Pertaining to	Mannheimia haemolytica
Study Purpose	Efficacy against respiratory disease
Product Administration	
Study Animals	Bovine
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	January 25, 2000

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Study Type	Efficacy
Pertaining to	Pasteurell multocida
Study Purpose	Efficacy against respiratory disease
Product Administration	
Study Animals	Bovine
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.
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Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions
Product Administration	
Study Animals	Bovine
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.
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