Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	7425.01
True Name	Clostridium Chauvoei-Septicum-Novyi-Sordellii-Perfringens Types C & D-Moraxella Bovis Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Alpha-7/MB-1 - No distributor specified
Date of Compilation Summary	September 04, 2019

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	*Clostridium chauvoei*
Study Purpose	Demonstration of efficacy against *Clostridium chauvoei*
Product Administration	
Study Animals	Bovine (cattle)
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 1, 1993

Study Type	Efficacy
Pertaining to	*Clostridium novyi*
Study Purpose	Demonstration of efficacy against *Clostridium novyi*
Product Administration	
Study Animals	Bovine (cattle)
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	November 2, 1992

Study Type	Efficacy
Pertaining to	*Clostridium perfringens* Type C
Study Purpose	Demonstration of efficacy against *Clostridium perfringens* Type C
Product Administration	
Study Animals	Bovine (cattle)
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 1, 1993

Study Type	Efficacy
Pertaining to	*Clostridium perfringens* Type D
Study Purpose	Demonstration of efficacy against *Clostridium perfringens* Type D
Product Administration	
Study Animals	Bovine (cattle)
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 1, 1993

Study Type	Efficacy
Pertaining to	*Clostridium septicum*
Study Purpose	Demonstration of efficacy against *Clostridium septicum*
Product Administration	
Study Animals	Bovine (cattle)
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 1, 1993

Study Type	Efficacy
Pertaining to	*Clostridium sordellii*
Study Purpose	Demonstration of efficacy against *Clostridium sordellii*
Product Administration	
Study Animals	Bovine (cattle)
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 1, 1993

Study Type	Efficacy
Pertaining to	*Moraxella bovis*
Study Purpose	Demonstration of efficacy against *Moraxella bovis*
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	October 20, 1995

Study Type	Efficacy
Pertaining to	*Moraxella bovis*
Study Purpose	Demonstration of efficacy with a 120 day duration of immunity against *Moraxella bovis*
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	August 26, 2004

Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions
Product Administration	
Study Animals	Bovine (cattle)
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	October 18, 1996