Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	7B23.00
True Name	Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordellii-Perfringens Types C & D-Haemophilus Somnus Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Bovilis Vision 8 Somnus - Intervet Mexico S.A. de C.V. Vision 8 Somnus with SPUR - Merck Animal Health
Date of Compilation Summary	June 04, 2020

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	To demonstrate effectiveness against disease caused by *C. chauvoei*
Product Administration	Subcutaneous and Intramuscular
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	May 26, 1998

Study Type	Efficacy
Pertaining to	*Clostridium haemolyticum*
Study Purpose	To demonstrate effectiveness against disease caused by *C. haemolyticum*
Product Administration	Subcutaneous and Intramuscular
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	Efficacy
Pertaining to	*Clostridium novyi*
Study Purpose	To demonstrate effectiveness against disease caused by *C. novyi*
Product Administration	Subcutaneous and Intramuscular
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	May 26, 1998

Study Type	Efficacy
Pertaining to	*Clostridium perfringens* Type C
Study Purpose	To demonstrate effectiveness against disease caused by *C. perfringens* Type C
Product Administration	Subcutaneous and Intramuscular
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	May 26, 1998

Study Type	Efficacy
Pertaining to	*Clostridium perfringens* Type D
Study Purpose	To demonstrate effectiveness against disease caused by *C. perfringens* Type D
Product Administration	Subcutaneous and Intramuscular
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	May 26, 1998

Study Type	Efficacy
Pertaining to	*Clostridium septicum*
Study Purpose	To demonstrate effectiveness against disease caused by *C. septicum*
Product Administration	Subcutaneous and Intramuscular
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	May 26, 1998

Study Type	Efficacy
Pertaining to	*Clostridium sordellii*
Study Purpose	To demonstrate effectiveness against disease caused by *C. sordellii*
Product Administration	Subcutaneous and Intramuscular
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	May 26, 1998

Study Type	Efficacy
Pertaining to	*Haemophilus Somnus*
Study Purpose	To demonstrate effectiveness against disease caused by *Haemophilus somnus*
Product Administration	Subcutaneous and Intramuscular
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	May 26, 1998

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety under field conditions.
Product Administration	Subcutaneous
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	February 5, 1999