

## **Summary of Studies Supporting USDA Product Licensure**

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	7410.00
True Name	Clostridium Chauvoei-Septicum-Novyi-Sordellii-Perfringens Types C & D Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Bar Vac 7 - 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.

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Study Type	Efficacy
Pertaining to	Clostridium chauvoei
<b>Study Purpose</b>	Demonstration of efficacy against Clostridium chauvoei
<b>Product Administration</b>	
Study Animals	
<b>Challenge Description</b>	
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	December 16, 1977

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Study Type	Efficacy
Pertaining to	Clostridium novyi
<b>Study Purpose</b>	Demonstration of efficacy against Clostridium novyi
<b>Product Administration</b>	
Study Animals	
<b>Challenge Description</b>	
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	December 16, 1977

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Study Type	Efficacy
Pertaining to	Clostridium perfringens Type C
<b>Study Purpose</b>	Demonstration of efficacy against Clostridium perfringens Type C
<b>Product Administration</b>	
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.
<b>USDA Approval Date</b>	December 16, 1977

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Study Type	Efficacy
Pertaining to	Clostridium perfringens Type D
Study Purpose	Demonstration of efficacy against Clostridium perfringens Type D
<b>Product Administration</b>	
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.
<b>USDA Approval Date</b>	December 16, 1977

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Study Type	Efficacy
Pertaining to	Clostridium septicum
Study Purpose	Demonstration of efficacy against Clostridium septicum
<b>Product Administration</b>	
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.
<b>USDA Approval Date</b>	December 16, 1977

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Study Type	Efficacy
Pertaining to	Clostridium sordellii
Study Purpose	Demonstration of efficacy against Clostridium sordellii
<b>Product Administration</b>	
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.
<b>USDA Approval Date</b>	December 16, 1977

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Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions
<b>Product Administration</b>	
Study Animals	
<b>Challenge Description</b>	
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.
<b>USDA Approval Date</b>	December 16, 1977

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Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions
<b>Product Administration</b>	
Study Animals	Bovine (cattle) including pregnant cattle
<b>Challenge Description</b>	
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 10, 1998

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