



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	7410.02
True Name	Clostridium Chauvoei-Septicum-Novyi-Sordellii-Perfringens Types C & D Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Caliber 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.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Clostridium chauvoei</i>
<b>Study Purpose</b>	Demonstration of efficacy against <i>Clostridium chauvoei</i>
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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>	November 23, 1998

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Clostridium novyi</i>
<b>Study Purpose</b>	Demonstration of efficacy against <i>Clostridium novyi</i>
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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>	November 23, 1998

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Clostridium perfringens</i> Type C
<b>Study Purpose</b>	Demonstration of efficacy against <i>Clostridium perfringens</i> Type C
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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>	November 23, 1998

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Clostridium perfringens</i> Type D
<b>Study Purpose</b>	Demonstration of efficacy against <i>Clostridium perfringens</i> Type D
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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>	November 23, 1998

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Clostridium septicum</i>
<b>Study Purpose</b>	Demonstration of efficacy against <i>Clostridium septicum</i>
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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>	November 23, 1998

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Clostridium sordellii</i>
<b>Study Purpose</b>	Demonstration of efficacy against <i>Clostridium sordellii</i>
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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>	November 23, 1998

<b>Study Type</b>	Safety
<b>Pertaining to</b>	All fractions
<b>Study Purpose</b>	To demonstrate safety under field conditions
<b>Product Administration</b>	
<b>Study Animals</b>	
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data are not available.

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