Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	7160.02
True Name	Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordellii-Perfringens Types C & D Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Clostribac 8 Gold - Zoetis de Chile S.A. UltraChoice 8 - No distributor specified UltraChoice 8 - SARL Belophram UltraChoice 8 - Zoetis Argentina UltraChoice 8 - Zoetis Hayvan Sagligi Ltd UltraChoice 8 - Zoetis Industria de Produtos UltraChoice 8 - Zoetis Mexico UltraChoice 8 - Zoetis Russia
Date of Compilation Summary	September 21, 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.

Study Type	Efficacy
Pertaining to	*Clostridium chauvoei*
Study Purpose	Demonstrate effectiveness against *Clostridium chauvoei*
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 3, 1999

Study Type	Efficacy
Pertaining to	*Clostridium chauvoei*
Study Purpose	Demonstrate effectiveness against *Clostridium chauvoei*
Product Administration	Subcutaneous
Study Animals	Ovine
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 26, 1999

Study Type	Efficacy
Pertaining to	*Clostridium haemolyticum*
Study Purpose	Demonstrate effectiveness against *Clostridium haemolyticum*
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 3, 1999

Study Type	Efficacy
Pertaining to	*Clostridium haemolyticum*
Study Purpose	Demonstrate effectiveness against *Clostridium haemolyticum*
Product Administration	Subcutaneous
Study Animals	Ovine
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 26, 1999

Study Type	Efficacy
Pertaining to	*Clostridium novyi*
Study Purpose	Demonstrate effectiveness against *Clostridium novyi*
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 3, 1999

Study Type	Efficacy
Pertaining to	*Clostridium novyi*
Study Purpose	Demonstrate effectiveness against *Clostridium novyi*
Product Administration	Subcutaneous
Study Animals	Ovine
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 26, 1999

Study Type	Efficacy
Pertaining to	*Clostridium perfringens* Type C
Study Purpose	Demonstrate effectiveness against *Clostridium perfringens* Type C
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 3, 1999

Study Type	Efficacy
Pertaining to	*Clostridium perfringens* Type C
Study Purpose	Demonstrate effectiveness against *Clostridium perfringens* Type C
Product Administration	Subcutaneous
Study Animals	Ovine
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 26, 1999

Study Type	Efficacy
Pertaining to	*Clostridium perfringens* Type D
Study Purpose	Demonstrate effectiveness against *Clostridium perfringens* Type D
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 3, 1999

Study Type	Efficacy
Pertaining to	*Clostridium perfringens* Type D
Study Purpose	Demonstrate effectiveness against *Clostridium perfringens* Type D
Product Administration	Subcutaneous
Study Animals	Ovine
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 26, 1999

Study Type	Efficacy
Pertaining to	*Clostridum septicum*
Study Purpose	Demonstrate effectiveness against *Clostridium septicum*
Product Administration	Subcutaneous
Study Animals	Ovine
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 26, 1999

Study Type	Efficacy
Pertaining to	*Clostridium septicum*
Study Purpose	Demonstrate effectiveness against *Clostridium septicum*
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 3, 1999

Study Type	Efficacy
Pertaining to	*Clostridium sordelli*
Study Purpose	Demonstrate effectiveness against *Clostridium sordelli*
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 3, 1999

Study Type	Efficacy
Pertaining to	*Clostridium sordelli*
Study Purpose	Demonstrate effectiveness against *Clostridium sordelli*
Product Administration	Subcutaneous
Study Animals	Ovine
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 26, 1999

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety in sheep under field conditions
Product Administration	Subcutaneous
Study Animals	Ovine
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 26, 1999

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety in sheep under field conditions
Product Administration	Subcutaneous
Study Animals	Ovine
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 26, 1999

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety in sheep under field conditions
Product Administration	Subcutaneous
Study Animals	Ovine
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 26, 1999

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety in cattle 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	May 27, 1999

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety in cattle 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	May 27, 1999

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety in cattle 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	May 27, 1999