



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Colorado Serum Company
USDA Vet Biologics Establishment Number	188
Product Code	7390.00
True Name	Clostridium Chauvoei-Septicum-Novyi-Sordellii Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Essential 4 - No distributor specified
Date of Compilation Summary	November 16, 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, Clostridium septicum, Clostridium novyi, and Clostridium sordellii
Study Purpose	Demonstrate efficacy against blackleg caused by C. chauvoei, malignant edema caused by C. septicum, black disease caused by C. novyi, and disease caused by C. sordellii
Product Administration	
Study Animals	Cattle, sheep, goats
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 18, 1983

Study Type	Safety
Pertaining to	All fractions
Study Purpose	Demonstrate safety of product under typical field conditions
Product Administration	
Study Animals	Cattle, sheep, goats
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 18, 1983