

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

Establishment Name	Colorado Serum Company
USDA Vet Biologics Establishment Number	188
Product Code	8305.00
True Name	Clostridium Perfringens Type D-Tetanus Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
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.

188 8305.00 Page 1 of 4

Study Type	Efficacy
Pertaining to	Clostridium Perfringens Type D
Study Purpose	Efficacy against Clostridium perfringens Type D
<b>Product Administration</b>	
Study Animals	Cattle, sheep, and goats
<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 required publication of data submitted after that date.
<b>USDA Approval Date</b>	October 1, 1984

188 8305.00 Page 2 of 4

Study Type	Efficacy
Pertaining to	Clostridium tetani
Study Purpose	Efficacy against Clostridium tetani
<b>Product Administration</b>	
Study Animals	Cattle, sheep, and goats
<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 required publication of data submitted after that date.
<b>USDA Approval Date</b>	October 1, 1984

188 8305.00 Page 3 of 4

Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under typical field conditions
<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 required publication of data submitted after that date.
<b>USDA Approval Date</b>	October 1, 1984

188 8305.00 Page 4 of 4