

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	2648.07
True Name	Escherichia Coli Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Bovine Pili Shield - Elanco US Inc.
Date of Compilation Summary	January 27, 2020

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	Escherichia Coli
Study Purpose	To demonstrate effectiveness against Escherichia Coli in calves
Product Administration	Pregnant cows
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 require publication of data submitted after that date.
USDA Approval Date	September 12, 1984

Study Type	Safety
Pertaining to	All
Study Purpose	To demonstrate safety under typical field conditions
Product Administration	
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 require publication of data submitted after that date.
USDA Approval Date	March 28, 1985