



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	2659.00
True Name	Haemophilus Somnus Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Somnu Shield - Elanco US Inc.
Date of Compilation Summary	June 24, 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.

Study Type	Efficacy
Pertaining to	<i>Haemophilus somnus</i>
Study Purpose	To demonstrate effectiveness against <i>Haemophilus somnus</i>
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	June 30, 1987

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	December 16, 1987

Study Type	Safety
Pertaining to	All
Study Purpose	To demonstrate safety under typical field conditions
Product Administration	
Study Animals	Bovine, 3 months of age or older, including pregnant cows and heifers.
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	October 15, 1991