Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	2556.00
True Name	Fusobacterium Necrophorum Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Elanco US Inc. Fusogard - Elanco Canada Limited - Elanco US Inc. Fusogard - Elanco US Inc. Fusogard - Elanco, Division Eli Lilly Canada, Inc. - Elanco US Inc. Fusogard - Eli Lilly of Brazil Ltd.- Division Elanco Animal Health - Elanco US Inc.
Date of Compilation Summary	February 18, 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	*Fusobacterium necrophorum*
Study Purpose	To demonstrate effectiveness against *Fusobacterium necrophorum*
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	October 31, 1997

Study Type	Efficacy
Pertaining to	*Fusobacterium necrophorum*
Study Purpose	To demonstrate effectiveness against liver abscesses due to *Fusobacterium necrophorum*
Product Administration	Subcutaneous
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 require publication of data submitted after that date.
USDA Approval Date	March 30, 1999

Study Type	Safety
Pertaining to	Fusobacterium necrophorum
Study Purpose	To demonstrate safety under typical field conditions
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-AHPIS prior to product licensure and met regulatory standards for acceptance at the time of submission. Study data, however, are no longer available.
USDA Approval Date	June 3, 1998