



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	2665.01
True Name	Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Lepto Shield 5 - Elanco US Inc. Lepto Shield 5 - Eli Lilly Interamerica Inc.
Date of Compilation Summary	May 28, 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>Leptospira canicola</i> , <i>Leptospira grippotyphosa</i> , <i>Leptospira icterohaemorrhagiae</i> , <i>Leptospira pomona</i>
Study Purpose	To demonstrate effectiveness against <i>Leptospira spp.</i>
Product Administration	
Study Animals	Bovine, swine
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 18, 1983

Study Type	Efficacy
Pertaining to	<i>Leptospira</i> Hardjo (type Hardjoprajitno)
Study Purpose	To demonstrate effectiveness against <i>Leptospira</i> Hardjo
Product Administration	
Study Animals	Bovine, Swine
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 18, 1983

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety of product under typical field conditions
Product Administration	Intramuscular
Study Animals	Swine, 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	July 16, 1992