



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	2671.02
True Name	Leptospira Canicola-Icterohaemorrhagiae Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	May 17, 2019

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>
Study Purpose	Demonstrate efficacy against <i>L. canicola</i>
Product Administration	Intramuscularly (IM) and subcutaneously (SQ)
Study Animals	Dogs
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. Study data, however, are no longer available.
USDA Approval Date	December 4, 1989

Study Type	Efficacy
Pertaining to	<i>Leptospira icterohaemorrhagiae</i>
Study Purpose	Demonstrate efficacy against <i>L. icterohaemorrhagiae</i>
Product Administration	Intramuscularly (IM) and subcutaneously (SQ)
Study Animals	Dogs
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. Study data, however, are no longer available.
USDA Approval Date	December 4, 1989

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions.
Product Administration	Intramuscularly (IM) and subcutaneously (SQ)
Study Animals	Dogs
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. Study data, however, are no longer available.
USDA Approval Date	December 4, 1989