

## **Summary of Studies Supporting USDA Product Licensure**

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	2668.00
True Name	Leptospira Canicola-Grippotyphosa-Icterohaemorrhagiae- Pomona Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Vanguard L4 - No distributor specified Vanguard L4 - Zoetis (Thailand) Limited Vanguard L4 - Zoetis Japan Inc. Vanguard L4 - Zoetis Mexico
Date of Compilation Summary	April 20, 2023

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	Leptospira Canicola
Study Purpose	Demonstrate effectiveness against L. canicola
<b>Product Administration</b>	
Study Animals	Canine
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 requires publication of data submitted after that date.
<b>USDA Approval Date</b>	December 22, 2004

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Study Type	Efficacy
Pertaining to	Leptospira Grippotypohosa
Study Purpose	Demonstrate effectiveness against L. grippotypohosa
<b>Product Administration</b>	
Study Animals	Canine
<b>Challenge Description</b>	
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 requires publication of data submitted after that date.
<b>USDA Approval Date</b>	June 03, 2004

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Study Type	Efficacy
Pertaining to	Leptospira Icterohaemorrhagiae
Study Purpose	Demonstrate effectiveness against L. icterohaemorrhagiae
<b>Product Administration</b>	Subcutaneously
Study Animals	Canine
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 requires publication of data submitted after that date.
USDA Approval Date	December 22, 2004

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Study Type	Efficacy
Pertaining to	Leptospira Pomona
Study Purpose	Demonstrate effectiveness against L. pomona
<b>Product Administration</b>	
<b>Study Animals</b>	Canine
<b>Challenge Description</b>	
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 requires publication of data submitted after that date.
<b>USDA Approval Date</b>	August 20, 2004

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Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety under field conditions
<b>Product Administration</b>	
Study Animals	Canine
<b>Challenge Description</b>	
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 requires publication of data submitted after that date.
<b>USDA Approval Date</b>	January 28, 2005

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