Summary of Studies Supporting USDA Product Licensure

Establishment Name	Diamond Animal Health, Inc.
USDA Vet Biologics Establishment Number	213
Product Code	4469.20
True Name	Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live & Killed Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Diamond Animal Health, Inc. Elanco Animal Health Master Guard 10 HB - Diamond Animal Health, Inc. Master Guard 10 HB - Elanco Animal Health Master Guard 10 HB - Elanco US, Inc. - Diamond Animal Health, Inc.
Date of Compilation Summary	April 01, 2022

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	Bovine Virus Diarrhea (BVD) Type 1
Study Purpose	To demonstrate efficacy of against BVD virus Type 1
Product Administration	Two doses by subcutaneous or intramuscular injection to healthy, susceptible cattle
Study Animals	Bovine
Challenge Description	BVD Type 1, NY-1 Strain (CVB-L lot 97-12)
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	January 27, 1999

Study Type	Efficacy
Pertaining to	Bovine Virus Diarrhea (BVD) Type 2
Study Purpose	To demonstrate efficacy of product for BVD virus Type 2
Product Administration	Two doses by subcutaneous or intramuscular injection
Study Animals	Bovine
Challenge Description	BVD virus Type 2, 890 Strain (lot 1444-57, from CVB-L lot 91-3)
Interval observed after challenge	14 days
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	January 27, 1999

Study Type	Efficacy
Pertaining to	Infectious Bovine Rhinotracheitis (IBR)
Study Purpose	To demonstrate efficacy of product for IBR virus
Product Administration	Two doses by intramuscular or subcutaneous injection
Study Animals	Bovine
Challenge Description	Cooper Challenge Strain IBR Virus Lot 50980
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	July 15, 1986

Study Type	Efficacy
Pertaining to	Leptospira canicola
Study Purpose	Demonstrate efficacy against L. canicola
Product Administration	One dose
Study Animals	Bovine
Challenge Description	NA
Interval observed after challenge	NA
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	January 5, 1983

Study Type	Efficacy
Pertaining to	Leptospira grippotyphosa
Study Purpose	Demonstrate efficacy against L. grippotyphosa
Product Administration	One dose
Study Animals	Bovine
Challenge Description	NA
Interval observed after challenge	NA
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	January 5, 1983

Study Type	Efficacy
Pertaining to	Leptospira hardjo
Study Purpose	Demonstrate efficacy against L. hardjo
Product Administration	One dose
Study Animals	Bovine
Challenge Description	Leptospira hardjo, Clay Center isolate
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	January 5, 1983

Study Type	Efficacy
Pertaining to	Leptospira icterohaemorrhagiae
Study Purpose	Demonstrate efficacy against L. icterohaemorrhagiae
Product Administration	One dose
Study Animals	Bovine
Challenge Description	NA
Interval observed after challenge	NA
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	January 5, 1983

Study Type	Efficacy
Pertaining to	Leptospira pomonaa
Study Purpose	Demonstrate efficacy against L. pomona
Product Administration	One dose
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 requires publication of data submitted after that date.
USDA Approval Date	January 5, 1983

Study Type	Efficacy
Pertaining to	Infectious Parainfluenza$_3$ (PI_3) Virus
Study Purpose	To demonstrate effectiveness against disease caused by infectious Parainfluenza$_3$ Virus
Product Administration	1 dose to calves 6-8 months of age.
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 requires publication of data submitted after that date.
USDA Approval Date	May 15, 1998

Study Type	Efficacy
Pertaining to	Bovine Respiratory Syncytial Virus (BRSV)
Study Purpose	To demonstrate effectiveness against disease caused by infectious Bovine Respiratory Syncytial Virus
Product Administration	1 dose to calves 6-8 months of age.
Study Animals	Bovine
Challenge Description	BRSV Strain 375
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	September 20, 1993

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety of product under typical use conditions
Product Administration	Two doses 14 days apart subcutaneously or intramuscularly
Study Animals	Bovine
Challenge Description	NA
Interval observed after challenge	NA
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	August 12, 1999

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>ALL</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate safety in pregnant cows</td></tr>
<tr><td>Product Administration</td><td>Two doses administered subcutaneously to heifers and cows, 1 dose prior to breeding and 1 dose during pregnancy at different trimesters. Heifers and cows were confirmed to be pregnant at administration during pregnancy.</td></tr>
<tr><td>Study Animals</td><td>Heifers and cows-separate groups vaccinated during each trimester. Similar sized groups in each trimester were maintained as controls.</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>Heifers and cows observed from the pre-breeding vaccination to post-breeding vaccination.</td></tr>
<tr><td>Results</td><td>First Trimester (≤93 days of gestation)
<table>
<tr><td></td><td>Vaccinate</td><td>Control</td></tr>
<tr><td>Enrolled</td><td>209</td><td>213</td></tr>
<tr><td>Excluded (not related to vaccination)</td><td>1</td><td>0</td></tr>
</table>
Second Trimester (94-187 days of gestation)
<table>
<tr><td></td><td>Vaccinate</td><td>Control</td></tr>
<tr><td>Enrolled</td><td>315</td><td>310</td></tr>
<tr><td>Excluded (not related to vaccination)</td><td>2</td><td>2</td></tr>
</table>
Third Trimester (188-250 days of gestation)
<table>
<tr><td></td><td>Vaccinate</td><td>Control</td></tr>
<tr><td>Enrolled</td><td>205</td><td>208</td></tr>
</table>
No adverse events were reported.</td></tr>
<tr><td>USDA Approval Date</td><td>March 5, 2013</td></tr>
</table>