Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	10L1.00
True Name	Lawsonia Intracellularis Vaccine, Avirulent Live Culture
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Enterisol Ileitis FF - Boehringer Ingelheim (Canada) Ltd.
Date of Compilation Summary	May 03, 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	Lawsonia Intracellularis
Study Purpose	Demonstration of duration of immunity
Product Administration	Oral
Study Animals	Twenty-eight pigs, three to four weeks old, divided into 19 vaccinates and 9 controls
Challenge Description	Challenged with live *Lawsonia intracellularis* 8 weeks after vaccination
Interval observed after challenge	Pigs were observed and tissues examined 21 days post 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 29, 2000

Study Type	Efficacy
Pertaining to	Lawsonia Intracellularis
Study Purpose	Demonstration of Efficacy
Product Administration	Administered orally via drinking water delivery system
Study Animals	Thirty-one pigs, three weeks old, divided into 20 vaccinates and 11 controls
Challenge Description	Pigs were challenged with live *Lawsonia intracellularis* 7 weeks after vaccination.
Interval observed after challenge	Pigs were observed daily for clinical signs of *Lawsonia intracellularis* for 14 days after challenge and then tissues were examined.
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 18, 2000

Study Type	Safety
Pertaining to	Lawsonia Intracellularis
Study Purpose	To demonstrate safety under field conditions
Product Administration	Oral drench or in drinking water
Study Animals	1025 total pigs, divided into 725 vaccinates and 300 controls
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	March 15, 2000