Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	7850.00
True Name	Escherichia Coli Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	J-Vac - Boehringer Ingelheim Animal Health do Brasil Ltda
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	*Escherichia coli*
Study Purpose	Demonstrate efficacy against the effects of endotoxemia caused by *E. coli* in Cattle
Product Administration	Subcutaneously (SQ) and Intramuscularly (IM)
Study Animals	
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	1993

Study Type	Efficacy
Pertaining to	*Escherichia coli*
Study Purpose	Demonstrate efficacy against mastitis caused by *E. coli* in Cattle
Product Administration	Subcutaneously (SQ) and Intramuscularly (IM)
Study Animals	
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 17, 1995

Study Type	Efficacy
Pertaining to	*Salmonella typhimurium*
Study Purpose	Demonstrate efficacy against the effects of endotoxemia caused by *Salmonella typhimurium* in Cattle
Product Administration	Subcutaneously (SQ) and Intramuscularly (IM)
Study Animals	
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	1992

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions.
Product Administration	Subcutaneously (SQ) and Intramuscularly (IM)
Study Animals	Cattle, including calves, steers, heifers, and dairy cows in various stages of gestation.
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	1993