

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	8601.00
True Name	Tetanus Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Tetguard - No distributor specified
Date of Compilation Summary	February 07, 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.

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Study Type	Efficacy
Pertaining to	Clostridium tetani
Study Purpose	Demonstration of efficacy against <i>Clostridium tetani</i> (tetanus)
	when administered to horses, cattle, sheep, or swine
Product Administration	
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	November 1, 1996

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Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions in horses
Product Administration	
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	July 19, 1989

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Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions in cattle, swine, and
	sheep
Product Administration	
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. Study data, however, are no longer available.
USDA Approval Date	Not applicable

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