



Summary of Studies Supporting USDA Product Licensure

Establishment Name	ARKO Laboratories, Ltd.
USDA Vet Biologics Establishment Number	337
Product Code	15R1.00
True Name	Escherichia Coli Vaccine, Avirulent Live Culture
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Edema Vac 100 - No distributor specified Edema Vac 500 - No distributor specified
Date of Compilation Summary	January 22, 2020

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	<i>Escherichia coli</i>
Study Purpose	Demonstrate effectiveness against edema disease caused by F18+ <i>E. coli</i>
Product Administration	Orally
Study Animals	Swine
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	December 23, 2003

Study Type	Safety
Pertaining to	<i>Escherichia coli</i>
Study Purpose	Demonstrate safety under typical field conditions
Product Administration	Orally
Study Animals	Swine
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	December 23, 2003