



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Colorado Serum Company
USDA Vet Biologics Establishment Number	188
Product Code	1011.00
True Name	Anthrax Spore Vaccine, Live Culture
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Pfizer Australia Pty Ltd
Date of Compilation Summary	February 14, 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.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Bacillus anthracis
<b>Study Purpose</b>	To demonstrate effectiveness against <i>Bacillus anthracis</i>
<b>Product Administration</b>	
<b>Study Animals</b>	
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	1958

<b>Study Type</b>	Safety
<b>Pertaining to</b>	Bacillus anthracis
<b>Study Purpose</b>	To demonstrate safety of Anthrax Spore Vaccine, Nonencapsulated Live Culture under typical use
<b>Product Administration</b>	
<b>Study Animals</b>	
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	1958