Summary of Studies Supporting USDA Product Licensure

Establishment Name	SolidTech Animal Health, Inc.
USDA Vet Biologics Establishment Number	604
Product Code	2772.I0
True Name	Moraxella Bovis Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	SolidBac Pinkeye IR/PR - No distributor specified SolidBac Pinkeye IR/PR - Zoetis Inc.
Date of Compilation Summary	January 31, 2022

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	*Moraxella bovis*
Study Purpose	Efficacy against pinkeye (infectious bovine keratoconjunctivitis) caused by *Moraxella bovis*
Product Administration	
Study Animals	Bovine
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 24, 1998

Study Type	Safety
Pertaining to	Moraxella Bovis Bacterin
Study Purpose	Demonstrate safety under field conditions
Product Administration	
Study Animals	Bovine
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	February 9, 2000

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>ALL</td></tr>
<tr><td>Study Purpose</td><td>To further demonstrate safety under field conditions</td></tr>
<tr><td>Product Administration</td><td>Single dose administered by subcutaneous (SQ) route in the neck or in the BASE of the ear.</td></tr>
<tr><td>Study Animals</td><td>Supplemental safety data.
Calves at 8 months of age. Two (2) independent study sites with 24 calves per site. Twelve (12) calves at each test location vaccinated SQ in the neck and 12 calves vaccinated SQ in the BASE of the ear.</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>21 days</td></tr>
<tr><td>Results</td><td>
<table>
<tr><td colspan="4">Injection Site Reactions Following Single Administration</td></tr>
<tr><td>Test Location</td><td>SQ Implant Site</td><td># Reactions Recorded/Total</td><td>Range in Size of Reaction (mm)</td></tr>
<tr><td>1</td><td>Neck</td><td>0/12</td><td>NA</td></tr>
<tr><td>1</td><td>Ear</td><td>0/12</td><td>NA</td></tr>
<tr><td>2</td><td>Neck</td><td>1/12*</td><td>1.5 x 0.75</td></tr>
<tr><td>2</td><td>Ear</td><td>0/12</td><td>NA</td></tr>
</table>
* Intralesional hair identified by histopathology. Hair could have been introduced during implanting procedure.
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<tr><td>USDA Approval Date</td><td>October 2, 2012</td></tr>
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