Summary of Studies Supporting USDA Product Licensure

Establishment Name	American Animal Health, Inc.
USDA Vet Biologics Establishment Number	315
Product Code	2760.01
True Name	Mycoplasma Bovis Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Myco-B One Dose - No distributor specified
Date of Compilation Summary	November 29, 2021

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	*Mycoplasma bovis*
Study Purpose	Efficacy against respiratory diseases caused by *M. bovis*
Product Administration	One dose, given subcutaneously
Study Animals	Calves, 2 months of age, 19 vaccinates and 19 controls
Challenge Description	*M. bovis* given 35 days after vaccination
Interval observed after challenge	Observed daily 2 days prior to and 14 days post-challenge. Lungs evaluated 14 days after challenge.
Results	The percent of the lung that was abnormal (consolidated) was calculated for every animal. One vaccinate and one control animal died post-challenge and were assigned the highest scores in the analysis but are not shown in the raw data.

Five-number summary of lung lesion scores

Group	Minimum	Q1	Median	Q3	Maximum
Vaccinates	0	1.3	3.8	14.4	71.7
Controls	2.5	9.8	13.7	20.5	53.23

Lung lesion scores (%), in order of rank

Vaccinate	Control
0	2.45
0	2.9
0	6.15
0.14	6.3
1.05	8.1
1.61	11.4
2.04	12.55
3.35	12.6
3.37	12.7
3.82	13.65
5.55	13.7
6.4	15.95
6.45	16.15
9.6	19.8
19.25	21.25
20.9	21.35
26.2	22.6
47.5	44.2
71.7	53.25

USDA Approval Date	January 28, 2009

Study Type	Efficacy
Pertaining to	*Mycoplasma bovis*
Study Purpose	Efficacy against arthritis caused by *M. bovis*
Product Administration	One dose, given subcutaneously
Study Animals	Cattle
Challenge Description	*M. bovis*
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	March 7, 2007

<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>Demonstrate safety of product under typical use conditions.</td></tr>
<tr><td>Product Administration</td><td>One dose, given subcutaneously.</td></tr>
<tr><td>Study Animals</td><td>487 calves total at 4 sites, 56 to 180 days old.</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed daily for clinical signs of local and systemic adverse reactions throughout the study. Palpation of injection sites was performed 3-6 days and 21-28 days post vaccination.</td></tr>
<tr><td>Results</td><td>Only injection site reactions were observed as follows:

<table>
<tr><td rowspan="2">Study Days</td><td colspan="4">Injection Site Swellings</td><td rowspan="2">Total Number Animals</td></tr>
<tr><td>0 cm</td><td><1.5 cm</td><td>1.5-5 cm</td><td>>5 cm</td></tr>
<tr><td>SD 3-6</td><td>256</td><td>58</td><td>167</td><td>6</td><td>487</td></tr>
<tr><td>SD 21-28</td><td>418</td><td>32</td><td>33</td><td>0</td><td>483#</td></tr>
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4 calves were not palpated.</td></tr>
<tr><td>USDA Approval Date</td><td>October 5, 2010</td></tr>
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