Summary of Studies Supporting USDA Product Licensure

Establishment Name	Addison Biological Laboratory, Inc.
USDA Vet Biologics Establishment Number	355
Product Code	2A77.00
True Name	Moraxella Bovoculi Bacterin
Tradename(s)/Distributor (if different from manufacturer)	
Date of Compilation Summary	January 12, 2017

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	Safety
Pertaining to	*Moraxella bovoculi* Bacterin
Study Purpose	Demonstrate safety of Bacterin under typical field use conditions
Product Administration	2 Doses administered subcutaneously 21 days apart. (Day 0 and Day 21)
Study Animals	611 head of cattle were vaccinated with at least 200 head in each of three distinct geographic regions. At least 1/3 of the animals vaccinated in each of the three regions were the minimum age recommended for product administration. Region 1 included 200 cattle. Region 2 included 201 cattle. Region 3 included 210 cattle.
Challenge Description	NA
Interval observed after challenge	Cattle were observed immediately after vaccination and once daily for 42 days after the first vaccination.
Results	

Injection Site Reactions Following 1st Dose of Vaccine

Region	Time following first vaccination when first observed	# of reactions recorded	Range of size of Reactions (mm)	Resolved prior to 2nd dose of vaccine
1	1 and 2 weeks following 1st dose	0	NA	NA
2	1 week following 1st dose	6	25-30 mm	6
2	2 weeks following 1st dose	2	20-24 mm	2

Injection Site Reactions Following 2nd Dose of Vaccine

Region	Time following first vaccination when first observed	# of reactions recorded	Range of size of Reactions (mm)	% Resolved prior to end of study or 2 weeks following first observation
1	1 week following 2nd dose	0	NA	NA

2	1 week following 2nd dose	30	25-75 mm	13
3	1 week following 2nd dose	5	40-51 mm	0

Injection Site Reactions First Observed on Day 42 (Final Day of Study)				
Region	**Time following first vaccination when first observed**	**# of reactions recorded**	**Range of size of Reactions (mm)**	**% Resolved**
1	3 weeks following 2nd dose	0	NA	NA
2	3 weeks following 2nd dose	17	7-39 mm	Unknown since calves were not followed past Day 42
3	3 weeks following 2nd dose	2	9-12 mm	

Adverse Events affirmed by licensee to have possible cause other than vaccine				
Event	**Region**	**Comments**	**# of Animals**	**Day of Study**
Respiratory Tract Disorder	1 & 3	Abnormal beathing; nasal discharge	3	Day 14 Region 1; Day 29 Region 3
Eye Disorder	2	Trauma induced corneal ulcer	2	Day 12
None	1, 2, 3		0	

NA is not applicable

USDA Approval Date	July 20, 2016