



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Addison Biological Laboratory, Inc.
USDA Vet Biologics Establishment Number	355
Product Code	2A77.01
True Name	Moraxella Bovoculi Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Agri Laboratories, Ltd.
Date of Compilation Summary	August 14, 2018

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	ALL
Study Purpose	Demonstrate safety under typical field conditions
Product Administration	2 Doses administered subcutaneously 21 days apart.
Study Animals	614 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.
Challenge Description	NA
Interval observed after challenge	Cattle were observed immediately after vaccination and once daily for 42 days after the first vaccination. If injection site reactions were present, cattle were observed up to 70 days post-vaccination.
Results	<p>Nineteen of the 614 animals developed injection site reactions following either the first or second dose of vaccine. Five cattle had injection site reactions following the first dose of vaccine and 14 cattle had reactions following the second dose of vaccine.</p> <p>Injection site reactions following the first dose resolved within 21 days.</p> <p>Injection site reactions following the second dose resolved within 49-70 days post vaccination or as indicated in the tables below.</p> <p>See the tables below.</p>
USDA Approval Date	June 22, 2018

Non-Vaccine Related Adverse Events*				
Event	Region	Comments	# of Animals	Day of Study
Respiratory Tract Disorder	1	Pneumonia	1	Day 7
Respiratory Tract Disorder	2	Pneumonia; Death;	2 deaths; 21 calves recovered	Days 5 and 6
Eye Disorder	2 and 3	Trauma induced corneal lesion(s)	3	Region 2: Day 34 Region 3: Day 4 Region 3: Day 39
Decreased Appetite	Region 3	Calf not coming to feed	1	Day 16

*Affirmed by licensee to have a cause other than the administered vaccine

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	Following 1st dose	0	NA	NA
2	1 week following 1st dose	1	43 mm	100%
2	2 weeks following 1st dose	1	34 mm	100%
2	3 weeks following 1st dose	1	20 mm	100%
3	3 weeks following 1st dose	1	12 mm	100%

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 (Monitoring extended to either 49 or 70 days)
1	1 week following 2nd dose	0	NA	NA
2	1 week following 2nd dose	4	45-67 mm	75% by Day 49
2	2 weeks following 2nd dose	1	52 mm	100% by Day 49
2	3 weeks following 2nd dose	4	20-45 mm	25% by Day 49
2	3 weeks following 2nd dose	4	23-32 mm	50% by Day 70
3	1 week following 2nd dose	0	NA	NA

Injection Site Reactions First Observed on Day 42 Resulting from 1st or 2nd Dose of Vaccine				
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	0	NA	NA
3	6 weeks following 1st dose	1	65 mm	Unknown since calves were not followed past Day 42
3	3 weeks following 2nd dose	1	50 mm	