Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	7A94.01
True Name	Corynebacterium Pseudotuberculosis Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	July 28, 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.

Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions
Product Administration	Two doses, administered intramuscularly 3 – 4 weeks apart
Study Animals	624 horses including 382 foals 4 months through ≤ 1 year of age
Challenge Description	Not applicable
Interval observed after challenge	Not applicable
Results	Horses were observed immediately after vaccination and once daily until 7 days after the second vaccination for systemic and injection site reactions. If injection site reactions were present at that day, the horses continued to be observed once daily until all injection site reactions, such as swellings, were completely resolved. Any injection site reaction was measured daily until the reaction resolved. See further detail on the next page.

Study 01-2013-CP-R

No systemic reactions were reported (0.0%).
No injection site reactions were reported (0.0%)

Age	Number of Vaccinates		Vaccinates With Transient Injection Site Reactions		Number of Normal Vaccinates	
	Missouri	North Dakota	1st dose	2nd dose	1st dose	2nd dose
≤ 1 year	104	0	0	0	104	104
≥ 2 year	18	145	0	0	163	163
Total	**122**	**145**	**0**	**0**	**267**	**267**

Study 01-2014-CP-R

No systemic reactions were reported (0.0%).

Transient local injection site non-painful swellings were reported. After the first vaccination, swellings were observed in 3 of 357 horses (0.8%) vaccinated within Texas. After the second vaccination, swellings were observed in 30 of 357 horses (8.4%) vaccinated either within Missouri or Texas. All swellings resolved within 10 days without medical treatment. Injection site swellings were not observed in horses vaccinated within North Dakota.
Footnoted below the table is the maximum size of the swelling observed.

Age	Number of Vaccinates			Vaccinates With Transient Injection Site Swelling		Number of Normal Vaccinates	
	Missouri	North Dakota	Texas	1st dose	2nd dose	1st dose	2nd dose
4 – 5 month	0	71	0	0	0	71	71
7 – 9 month	0	0	49	0	6**	49	43
1 year	87	0	71	3*	24***	158	137
≥ 2 year	0	76	3	0	0	76	76
Total	**87**	**147**	**123**	**3**	**30**	**354**	**327**

*All horses vaccinated within Missouri. A swelling in 1 horse (5.5cm in diameter) resolved in 8 days. A 0.7cm in diameter in one horse and a 4cm in diameter swelling in another horse were observed and each resolved in 10 days.
**All horses vaccinated within Texas. Swellings in 5 horses (all <2 inches in diameter) resolved in 4 days; a 2 inches in diameter swelling in one horse resolved in 5 days.
***23 horses vaccinated within Texas: 2 inches in diameter swelling in one horse; 3 inches in diameter swellings in 12 horses; 4 inches in diameter swellings in 4 horses; 5 inches in diameter swellings in 5 horses; and a 6 inches in diameter swelling in one horse. These injection site swellings resolved in 4 to 6 days.
1 horse vaccinated in Missouri: A 3.7cm x 7.3cm swelling resolved in 4 days.

USDA Approval Date	November 18, 2014

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>All fractions</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate safety under field conditions</td></tr>
<tr><td>Product Administration</td><td>Two doses, given intramuscularly, 3 – 4 weeks apart</td></tr>
<tr><td>Study Animals</td><td>152 horses at 3-6 months of age</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>Not applicable</td></tr>
<tr><td>Results</td><td>152 horses were enrolled in California, Texas, Missouri and North Dakota.

Horses were observed continuously for 6 hours after each injection and monitored daily for the duration of the study injection site reactions. Any injection site reaction was measured daily until the reaction resolved.

After first vaccination, swellings were observed in 6 of the 152 horses. After the second vaccination, swellings were observed in 17 of the 152 horses. No injection site swellings were observed in Texas or North Dakota.

<table>
<tr><td rowspan="2">Location</td><td rowspan="2">Number of Vaccinates</td><td colspan="2">Number of Vaccinates with Transient Injection Site Swelling</td></tr>
<tr><td>1st Dose</td><td>2nd Dose</td></tr>
<tr><td>California</td><td>52</td><td>0</td><td>3</td></tr>
<tr><td>Texas</td><td>14</td><td>0</td><td>0</td></tr>
<tr><td>Missouri</td><td>46</td><td>6</td><td>14</td></tr>
<tr><td>North Dakota</td><td>40</td><td>0</td><td>0</td></tr>
<tr><td>Totals</td><td>152</td><td>6</td><td>17</td></tr>
</table>
Injection Site Reactions by Administration of Vaccination*
<table>
<tr><td>Vaccination</td><td><1.5 cm in size</td><td>1.5-5 cm in size</td><td>>5 cm in size</td></tr>
<tr><td>First</td><td>0</td><td>2</td><td>4</td></tr>
<tr><td>Second</td><td>1</td><td>5</td><td>11</td></tr>
</table>
*Swellings in 19 foals resolved 3-14 days after administration. Three foals had injection site reactions during the first and second vaccination.A A draining abscess began 2 days after the second vaccination and resolved After 7 days without treatment.</td></tr>
</table>

Other Adverse Events (counted once per animal)

Adverse Event†	Number of Adverse Events
Abdominal Pain/Colic*	1
Injection site pain	4
Trauma NOS[¥]	4
Lethargy**	2
Anorexia**	1
General Pain**	1

NOS = Not otherwise specified

†VeDDRA Low Level Term or Preferred term used for reporting adverse events.

*One foal exhibited mild colic 5 days after second vaccination that recovered immediately following treatment with Buscopan.

[¥]Three foals had lacerations unrelated to vaccine administration as affirmed by licensee.

** One foal experienced lethargy, anorexia, and general pain on the day after the first injection that fully resolved the next day.

USDA Approval Date	December 2, 2019