Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	7460.00
True Name	Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordellii-Perfringens Types C & D-Mannheimia Haemolytica Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	One Shot Ultra 8 - Nasser Mohamed Nasser Co. One Shot Ultra 8 - No distributor specified One Shot Ultra 8 - Zoetis Argentina One Shot Ultra 8 - Zoetis Colombia S.A.S. One Shot Ultra 8 - Zoetis Hayvan Sagligi Ltd One Shot Ultra 8 - Zoetis Mexico One Shot Ultra 8 - Zoetis Russia
Date of Compilation Summary	July 05, 2023

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	*Clostridium chauvoei*
Study Purpose	Demonstrate effectiveness against *Clostridium chauvoei*
Product Administration	Subcutaneous
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 3, 1999

Study Type	Efficacy
Pertaining to	*Clostridium haemolyticum*
Study Purpose	Demonstrate effectiveness against *Clostridium haemolyticum*
Product Administration	Subcutaneous
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 3, 1999

Study Type	Efficacy
Pertaining to	*Clostridium novyi*
Study Purpose	Demonstrate effectiveness against *Clostridium novyi*
Product Administration	Subcutaneous
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 3, 1999

Study Type	Efficacy
Pertaining to	*Clostridium perfringens* Type C
Study Purpose	Demonstrate effectiveness against *Clostridium perfringens* Type C
Product Administration	Subcutaneous
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 3, 1999

Study Type	Efficacy
Pertaining to	*Clostridium perfringens* Type D
Study Purpose	Demonstrate effectiveness against *Clostridium perfringens* Type D
Product Administration	Subcutaneous
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 3, 1999

Study Type	Efficacy
Pertaining to	*Clostridium septicum*
Study Purpose	Demonstrate effectiveness against *Clostridium septicum*
Product Administration	Subcutaneous
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 3, 1999

Study Type	Efficacy
Pertaining to	*Clostridium sordelli*
Study Purpose	Demonstrate effectiveness against *Clostridium sordelli*
Product Administration	Subcutaneous
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 3, 1999

Study Type	Efficacy
Pertaining to	*Mannheimia haemolytica*
Study Purpose	Demonstrates effectiveness against *Mannheimia haemolytica*
Product Administration	Subcutaneous
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	June 21, 1991

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Mannheimia haemolytica</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate efficacy against respiratory disease caused by Mannheimia haemolytica</td></tr>
<tr><td>Product Administration</td><td>One dose administered subcutaneously</td></tr>
<tr><td>Study Animals</td><td>9 vaccinates and 11 controls calves</td></tr>
<tr><td>Challenge Description</td><td>M. haemolytica administered 14 days post-vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed daily from days 12 through 18 post-challenge then lung lesions were evaluated.</td></tr>
<tr><td>Results</td><td>Lung lesions (%) was the efficacy variable.

Lung lesions:
<table>
<tr><th></th><th>Minimum</th><th>25th Percentile</th><th>Median</th><th>75th Percentile</th><th>Maximum</th></tr>
<tr><td>Placebo</td><td>1.6</td><td>5.6</td><td>9.5</td><td>17.1</td><td>92.9</td></tr>
<tr><td>Vaccinates</td><td>0.4</td><td>1.0</td><td>1.7</td><td>2.6</td><td>14.8</td></tr>
</table>
Mortality:
Controls: 2/11 (18.2%)
Vaccinates: 0/9 (0%)

See individual data attached</td></tr>
<tr><td>USDA Approval Date</td><td>08/20/1999</td></tr>
</table>

Lung Lesions and Mortality by Treatment and Animal

Controls

Animal	Lung Lesions (%)	Mortality Post-Challenge
281	9.7	No
600	10.1	No
603	4.9	No
605	17.1	No
606	27.0	Yes
610	92.9	Yes
615	7.7	No
616	9.2	No
618	5.6	No
627	1.6	No
628	9.5	No

Vaccinates

Animal	Lung Lesions (%)	Mortality Post-Challenge
269	0.4	No
279	1.0	No
287	2.1	No
297	1.7	No
601	0.4	No
602	2.6	No
604	1.0	No
609	9.5	No
625	14.8	No

<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 in cattle under field conditions</td></tr>
<tr><td>Product Administration</td><td>Two doses administered subcutaneously 28 days apart</td></tr>
<tr><td>Study Animals</td><td>200 crossbred beef heifers</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>Calves were observed for one hour after vaccination and daily throughout the study for adverse events. Animals were examined for injection site reactions on days 14, 28, and 42 post-vaccination (left side) and day 14 post-vaccination (right side).</td></tr>
<tr><td>Results</td><td>Number of Animals with Adverse Events

<table>
<tr><th></th><th>Nasal Discharge</th><th>Diarrhea</th><th>Respiration Rate</th><th>Lameness</th><th>Leg Abscess</th></tr>
<tr><td>Vaccinates</td><td>55</td><td>1</td><td>1</td><td>1</td><td>1</td></tr>
</table>
All observations were affirmed by licensee to be due to causes other than vaccination.

Number of Animals with Injection Site Reactions

<table>
<tr><th rowspan="2">Vaccinates</th><th colspan="3">Days Post-Vaccination</th></tr>
<tr><th>14</th><th>28</th><th>42</th></tr>
<tr><td>Left Side</td><td>129</td><td>41</td><td>13</td></tr>
<tr><td>Right Side</td><td>153</td><td>-</td><td>-</td></tr>
</table>
All injection site reactions were transient and under 4 cm in diameter.</td></tr>
<tr><td>USDA Approval Date</td><td>09/08/1999</td></tr>
</table>

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<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 in cattle under field conditions</td></tr>
<tr><td>Product Administration</td><td>Two doses administered subcutaneously 28 days apart</td></tr>
<tr><td>Study Animals</td><td>196 crossbred beef heifers</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>Calves were observed for one hour after vaccination and daily throughout the study for adverse events. Animals were examined for injection site reactions on days 14, 28, and 42 post-vaccination (left side) and day 14 post-vaccination (right side).</td></tr>
<tr><td>Results</td><td><u>Number of Animals with Adverse Events</u>

<table>
<tr><td></td><td>Lameness</td><td>Pink eye</td><td>Depression</td></tr>
<tr><td>Vaccinates</td><td>15</td><td>1</td><td>1</td></tr>
</table>
All observations were affirmed by licensee to be due to causes other than vaccination.

<u>Number of Animals with Injection Site Reactions</u>

<table>
<tr><td rowspan="2">Vaccinates</td><td colspan="3">Days Post-Vaccination</td></tr>
<tr><td>14</td><td>28</td><td>42</td></tr>
<tr><td>Left Side</td><td>74</td><td>7</td><td>3</td></tr>
<tr><td>Right Side</td><td>94</td><td>-</td><td>-</td></tr>
</table>
All injection site reactions were transient and under 2 cm in diameter.</td></tr>
<tr><td>USDA Approval Date</td><td>09/08/1999</td></tr>
</table>

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<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 in cattle under field conditions</td></tr>
<tr><td>Product Administration</td><td>Two doses administered 28 days apart</td></tr>
<tr><td>Study Animals</td><td>200 crossbred beef heifers</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>Calves were observed for one hour after vaccination and daily throughout the study for adverse events. Animals were examined for injection site reactions on days 14, 28, and 42 post-vaccination (left side) and day 14 post-vaccination (right side).</td></tr>
<tr><td>Results</td><td><u>Number of Animals with Adverse Events</u>

<table>
<tr><td></td><td>Lameness</td><td>Ring worm</td></tr>
<tr><td>Vaccinates</td><td>1</td><td>1</td></tr>
</table>
All observations were affirmed by licensee to be due to causes other than vaccination.

<u>Number of Animals with Injection Site Reactions</u>

<table>
<tr><td rowspan="2">Vaccinates</td><td colspan="3">Days Post-Vaccination</td></tr>
<tr><td>14</td><td>28</td><td>42</td></tr>
<tr><td>Left Side</td><td>80</td><td>22</td><td>7</td></tr>
<tr><td>Right Side</td><td>95</td><td>-</td><td>-</td></tr>
</table>
All injection site reactions were transient and under 4 cm in diameter.</td></tr>
<tr><td>USDA Approval Date</td><td>09/08/1999</td></tr>
</table>