Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	12M5.E0
True Name	Bursal Disease-Newcastle Disease-Bronchitis-Reovirus Vaccine, Standard & Variant, Mass Type, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Not Listed - No distributor specified
Date of Compilation Summary	August 20, 2019

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	Infectious bursal disease virus
Study Purpose	Demonstrate efficacy against standard infectious bursal disease in progeny
Product Administration	
Study Animals	Chicken
Challenge Description	STC IBDV
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	1 June 1995

Study Type	Efficacy
Pertaining to	Infectious bursal disease virus
Study Purpose	Demonstrate efficacy against variant infectious bursal disease in progeny
Product Administration	
Study Animals	Chicken
Challenge Description	Variant IBDV
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	11 April 1996

Study Type	Efficacy
Pertaining to	Infectious bursal disease virus
Study Purpose	Demonstrate efficacy against standard infectious bursal disease in vaccinates
Product Administration	
Study Animals	Chicken
Challenge Description	STC IBDV
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	1 June 1995

Study Type	Efficacy
Pertaining to	Infectious bursal disease virus
Study Purpose	Demonstrate efficacy against variant infectious bursal disease in vaccinates
Product Administration	
Study Animals	Chicken
Challenge Description	Variant IBDV
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	11 April 1996

Study Type	Efficacy
Pertaining to	Infectious bronchitis
Study Purpose	Demonstrate efficacy against infectious bronchitis Massachusetts type
Product Administration	
Study Animals	Chickens
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	11 August 1987

Study Type	Efficacy
Pertaining to	Newcastle disease virus
Study Purpose	Demonstrate efficacy against Newcastle disease
Product Administration	intramuscularly
Study Animals	Chickens
Challenge Description	GB Texas
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	11 August 1987

Study Type	Efficacy
Pertaining to	Newcastle disease virus
Study Purpose	Demonstrate efficacy against Newcastle disease in progeny
Product Administration	
Study Animals	Chickens
Challenge Description	GB Texas
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	21 July 1994

Study Type	Efficacy
Pertaining to	Reovirus
Study Purpose	Demonstrate efficacy against Reovirus in progeny of vaccinated birds
Product Administration	
Study Animals	Chickens
Challenge Description	Avian Reovirus
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	29 November 1994

Study Type	Efficacy
Pertaining to	Reo virus
Study Purpose	Demonstrate efficacy against Reo virus in vaccinates
Product Administration	
Study Animals	Chicken
Challenge Description	Avian Reo virus
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	29 November 1994

<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>To demonstrate safety under field conditions</td></tr>
<tr><td>Product Administration</td><td>One dose administered as an intramuscular or subcutaneous injection at 11 to 14 weeks of age.</td></tr>
<tr><td>Study Animals</td><td>Approximately 54,985 commercial broiler breeder pullets:
Site A: Vaccinates: 9,477, Controls: 9,891
Site B: Vaccinates: 8,405, Controls: 8,420
Site C: Vaccinates: 9,479, Controls: 9,313</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after vaccination</td><td>Birds were monitored daily for mortality through 21 days after vaccination.</td></tr>
<tr><td>Results</td><td>Results of Field Safety Study
<table>
<tr><th>Description</th><th>Site</th><th>Route</th><th>Total placed</th><th>% Mortality</th><th>Overall %</th></tr>
<tr><td rowspan="3">Vaccinates</td><td>Site A</td><td>IM</td><td>9,477</td><td>1.17*</td><td rowspan="3">1.01</td></tr>
<tr><td>Site B</td><td>SC</td><td>8,405</td><td>1.06</td></tr>
<tr><td>Site C</td><td>IM</td><td>9,479</td><td>0.73</td></tr>
<tr><td rowspan="3">Controls</td><td>Site A</td><td>IM</td><td>9,891</td><td>0.53</td><td rowspan="3">1.04</td></tr>
<tr><td>Site B</td><td>SC</td><td>8,420</td><td>1.27</td></tr>
<tr><td>Site C</td><td>IM</td><td>9,313</td><td>1.00</td></tr>
</table>
*Culling due to pre-existing breast blisters resulted in higher mortality and not attributed to vaccination as affirmed by licensee.

No other adverse events were observed.</td></tr>
<tr><td>USDA Approval Date</td><td>8 November 2018</td></tr>
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