



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	48D6.10
True Name	Newcastle-Bronchitis Vaccine, Mass Type, Killed Virus, Salmonella Enteritidis Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Poulvac SE-ND-IB - No distributor specified Poulvac SE-ND-IB - Zoetis Argentina Poulvac SE-ND-IB - Zoetis Industria de Productos
Date of Compilation Summary	March 27, 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.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious bronchitis virus
<b>Study Purpose</b>	Demonstrate efficacy against infectious bronchitis, Mass. type
<b>Product Administration</b>	
<b>Study Animals</b>	Chicken
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	24 February 1999

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Newcastle disease virus
<b>Study Purpose</b>	Demonstrate efficacy against Newcastle disease
<b>Product Administration</b>	
<b>Study Animals</b>	Chicken
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	24 February 1999

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Salmonella enteritidis</i>
<b>Study Purpose</b>	Demonstrate efficacy against <i>S. enteritidis</i> colonization of internal organs
<b>Product Administration</b>	
<b>Study Animals</b>	Chickens
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	24 February 1999

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Salmonella enteritidis</i>
<b>Study Purpose</b>	Demonstrate efficacy against <i>S. enteritidis</i> colonization of internal organs, including reproductive tract and intestines
<b>Product Administration</b>	
<b>Study Animals</b>	Chicken
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	1 June 1999

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	Demonstrate safety under typical field conditions
<b>Product Administration</b>	
<b>Study Animals</b>	Chicken
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	28 June 1999