

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	1776.10
True Name	Newcastle-Bronchitis Vaccine, Mass Type, Killed Virus
Tradename(s) / Distributor or	Poulvac I N + B - Amadeo Buongermini
Subsidiary (if different from manufacturer)	Poulvac I N + B - No distributor specified
	Poulvac I N + B - Zoetis (Thailand) Limited
Date of Compilation Summary	February 12, 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	Efficacy
Pertaining to	Infectious bronchitis virus
Study Purpose	Demonstrate efficacy against infectious bronchitis, Mass. type
Product Administration	
Study Animals	Chicken
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	24 February 1999

Study Type	Efficacy
Pertaining to	Newcastle disease virus
Study Purpose	Demonstrate efficacy against Newcastle disease
Product Administration	
Study Animals	Chicken
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	24 February 1999

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under typical field conditions
Product Administration	
Study Animals	Chicken
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	28 June 1999