



Summary of Studies Supporting USDA Product Licensure

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| Establishment Name | Phibro Animal Health Corporation |
| USDA Vet Biologics Establishment Number | 301 |
| Product Code | 1081.00 |
| True Name | Bordetella Bronchiseptica Vaccine, Avirulent Live Culture |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | Phibro Animal Health |
| Date of Compilation Summary | October 18, 2021 |

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.

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| Study Type | Efficacy |
| Pertaining to | Bordetella bronchiseptica |
| Study Purpose | To demonstrate efficacy in piglets against Bordetella bronchiseptica |
| Product Administration | |
| Study Animals | Porcine |
| 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 | 1988 |

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| Study Type | Safety |
| Pertaining to | Bordetella bronchiseptica |
| Study Purpose | To demonstrate safety under typical field conditions |
| Product Administration | |
| Study Animals | Porcine |
| 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 | May 23, 1989 |