

## Summary of Studies Supporting USDA Product Licensure

| Establishment Name  | Zoetis Inc.   |
|---|---|
| USDA Vet Biologics<br>Establishment Number                                      | 190   |
| Product Code  | 1081.00   |
| True Name   | Bordetella Bronchiseptica Vaccine, Avirulent Live Culture                                       |
| Tradename(s) / Distributor or<br>Subsidiary<br>(if different from manufacturer) | Protech Bronchi-Shield I - Zoetis New Zealand Ltd<br>Vanguard B (IN) - No distributor specified |
| Date of Compilation<br>Summary  | March 16, 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.

| Study Type                    | Efficacy   |
|-------------------------------|--|
| Pertaining to                 | Bordetella bronchiseptica (B. bronchiseptica)  |
| Study Purpose                 | To demonstrate effectiveness against respiratory disease caused  |
|                               | by <i>B. bronchiseptica</i>  |
| <b>Product Administration</b> | Intranasal   |
| Study Animals                 |  |
| <b>Challenge Description</b>  |  |
| Interval observed after       |  |
| challenge                     |  |
| Results                       | Study data were evaluated by USDA-APHIS prior to product<br>licensure and met regulatory standards for acceptance at the time<br>of submission. No data are published because this study was<br>submitted to USDA-APHIS prior to January 1, 2007, and APHIS<br>only requires publication of data submitted after that date |
| USDA Approval Date            | December 16, 1992  |

| Study Type                    | Safety  |
|-------------------------------|---|
| Pertaining to                 | ALL   |
| Study Purpose                 | To evaluate safety under typical field conditions.  |
| <b>Product Administration</b> | Intranasal  |
| Study Animals                 |   |
| <b>Challenge Description</b>  |   |
| Interval observed after       |   |
| challenge                     |   |
| Results                       | Study data were evaluated by USDA-APHIS prior to product<br>licensure and met regulatory standards for acceptance at the time<br>of submission. No data are published because this study was<br>submitted to USDA-APHIS prior to January 1, 2007, and APHIS<br>only requires publication of data submitted after that date. |
| USDA Approval Date            | December 16, 1992   |