

Summary of Studies Supporting USDA Product Licensure

| Establishment Name | Colorado Serum Company |
|---|---|
| USDA Vet Biologics Establishment Number | 188 |
| Product Code | 2119.00 |
| True Name | Campylobacter Fetus-Jejuni-Chlamydia Abortus Bacterin |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | Enzabort EAE-Vibrio - No distributor specified |
| Date of Compilation Summary | December 28, 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.

188 2119.00 Page 1 of 3

| Study Type | Efficacy |
|-------------------------------|---|
| Pertaining to | Campylobacter fetus, Campylobacter jejuni, Chlamydia abortus |
| Study Purpose | To demonstrate efficacy against diseases caused by |
| - | Campylobacter fetus, Campylobacter jejuni, and Chlamydia |
| | abortus |
| Product Administration | |
| Study Animals | Female Sheep |
| 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 | October 10, 1984 |

188 2119.00 Page 2 of 3

| Study Type | Safety |
|-------------------------------|---|
| Pertaining to | All Fractions |
| Study Purpose | To demonstrate safety of product under typical field conditions |
| Product Administration | |
| Study Animals | Female Sheep |
| 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 | October 10, 1984 |

188 2119.00 Page 3 of 3