



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Hygieia Biological Laboratories
USDA Vet Biologics Establishment Number	407
Product Code	2851.00
True Name	Streptococcus Uberis Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	DUNPREBAC Uberis - Duncan Labs Animal Health
Date of Compilation Summary	March 30, 2023

**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>	Safety
<b>Pertaining to</b>	All
<b>Study Purpose</b>	Demonstrate safety under field conditions
<b>Product Administration</b>	Three doses injected subcutaneously at four to six-week intervals
<b>Study Animals</b>	7,322 pregnant dairy cows and heifers in third trimester at three geographically distinct farms
<b>Challenge Description</b>	Not Applicable
<b>Interval observed after challenge</b>	Observation immediately after each administration for systemic reactions and injection site swellings
<b>Results</b>	No injection site swelling and no systemic reactions were reported in any animal immediately following vaccination or prior to the next administration
<b>USDA Approval Date</b>	May 3, 2012