**Summary of Studies Supporting USDA Product Licensure**

<table>
<thead>
<tr>
<th>Establishment Name</th>
<th>Intervet Inc.</th>
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</thead>
<tbody>
<tr>
<td>USDA Vet Biologics</td>
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<tr>
<td>Establishment Number</td>
<td>165A</td>
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<tr>
<td>Product Code</td>
<td>19U5.P1</td>
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<tr>
<td>True Name</td>
<td>Porcine Epidemic Diarrhea Vaccine, RNA Particle Platform</td>
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<tr>
<td>Tradename(s) / Distributor or Subsidiary (if different from manufacturer)</td>
<td>Intervet Mexico S.A. de C.V. Merck Animal Health Merck Sharpe and Dohme (MSD)</td>
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<tr>
<td>Date of Compilation Summary</td>
<td>December 28, 2021</td>
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</tbody>
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**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**  | Safety  
---|---  
**Pertaining to**  | All  
**Study Purpose**  | Demonstrate safety of product under typical use conditions.  
**Product Administration**  | 2 doses administered intramuscularly (IM) 3 weeks apart.  
**Study Animals**  | 400 pigs, 3 weeks of age, distributed among 2 study sites.  
**Challenge Description**  | Not applicable  
**Interval observed after challenge**  | Animals were observed one hour after administration for immediate adverse reactions, at 48-72 hours and on 7 days post-vaccination for local or systemic reactions after each administration. 21 days post-vaccination the injection sites were palpated for all animals.  
**Results**  | Frequency of adverse events out of 799* possible (400 pigs)  
Injection site swelling**  | 7  
Lethargy  | 6  
Death***  | 7  
Anorexia  | 5  
Lameness  | 4  
Swollen join  | 3  
Loss of condition  | 6  
Cough  | 1  
No Adverse Events  | 755  

*1 pig died prior to 2nd vaccination  
**3 resolved by the end of study, 5 were reported at the end of the study after 2nd vaccination  
***Deaths affirmed by study cooperator as not attributable to vaccine.  

**USDA Approval Date**  | May 15, 2014