Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1A89.R1
True Name	Bursal Disease-Marek's Disease-Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Vaxxitek HVT + IBD + ND - No distributor specified
Date of Compilation Summary	July 23, 2019

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	Infectious Bursal disease virus (IBDV), standard
Study Purpose	Demonstrate efficacy against standard bursal disease
Product Administration	One dose administered *in ovo* at 18-19 days of embryonation
Study Animals	Specific pathogen-free eggs divided into 2 groups of 30 each Group 2 vaccinated with product and challenged Group 5 sham vaccinated and challenged (control)
Challenge Description	IBDV standard challenge administered 31 days after vaccination (28 days of age)
Interval observed after challenge	Observed daily for 4 days and then examined for gross bursal lesions
Results	Vaccinates and controls were evaluated in terms of bursal disease grossly observable lesions per the criteria in 9 CFR 113.331(c). Birds with gross observable lesions: Group 2: 2/30 Group 5: 30/30 Requirements of 9 CFR 113.331(c) were met. Raw data on attached page
USDA Approval Date	June 12, 2017

Raw data shown below for birds classified as positive. All other birds normal.

Group/Bird	Peri-Bursal Edema	Edema	Macroscopic Hemorrhage	Bursal Disease Score	Comments
2/1	X			Positive	
2/2			X	Positive	dead
5/1	X			Positive	
5/2		X	X	Positive	
5/3		X		Positive	
5/4	X			Positive	
5/5	X			Positive	
5/6		X		Positive	
5/7	X			Positive	
5/8		X		Positive	
5/9		X		Positive	
5/10		X		Positive	
5/11	X			Positive	
5/12	X			Positive	
5/13		X		Positive	
5/14		X		Positive	
5/15		X		Positive	
5/16	X			Positive	
5/17	X		X	Positive	
5/18	X			Positive	
5/19	X			Positive	
5/20			X	Positive	dead
5/21		X		Positive	
5/22	X			Positive	dead
5/23	X			Positive	
5/24	X			Positive	
5/25	X			Positive	
5/26	X			Positive	dead
5/27	X			Positive	
5/28	X			Positive	
5/29	X			Positive	
5/30			X	Positive	dead

Study Type	Efficacy
Pertaining to	Bursal disease virus
Study Purpose	Demonstrate efficacy against bursal disease, standard
Product Administration	One dose administered subcutaneous route
Study Animals	1-day-old SPF birds divided into 2 groups Group 3 vaccinated with test product and challenged Group 5 sham vaccinated and challenged (control)
Challenge Description	IBDV standard challenge administered at 29 days of age
Interval observed after challenge	Observed daily for 4 days and necropsied to examine for gross bursal lesions
Results	Vaccinates and controls were evaluated in terms of bursal disease grossly observable lesions per the criteria in 9 CFR 113.331(c). Birds with gross observable lesions: Group 3: 1/30 Group 5: 29/30 Requirements of 9 CFR 113.331(c) were met. Raw data on attached page
USDA Approval Date	December 5, 2017

Raw data shown below for birds classified as positive. All other birds normal.

Group/Bird	Bursal Disease Score	Comments
3/1	Positive	Edema
5/1	Positive	Edema
5/2	Positive	Edema
5/3	Positive	Edema
5/4	Positive	Edema
5/5	Positive	Edema
5/6	Positive	Edema
5/7	Positive	Edema
5/8	Positive	Necrotic
5/9	Positive	Necrotic
5/10	Positive	Edema
5/11	Positive	Edema
5/12	Positive	Edema
5/13	Positive	Edema
5/14	Positive	Edema
5/15	Positive	Edema
5/16	Positive	Edema
5/17	Positive	Edema
5/18	Positive	Edema
5/19	Positive	Edema
5/20	Positive	Edema
5/21	Positive	Edema
5/22	Positive	Edema
5/23	Positive	Edema
5/24	Positive	Edema
5/25	Positive	Edema
5/26	Positive	Edema
5/27	Positive	Edema
5/28	Positive	Edema
5/29	Positive	Edema

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Bursal disease virus variant E</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate efficacy against bursal disease variant E</td></tr>
<tr><td>Product Administration</td><td>One dose administered at day of age by the subcutaneous route</td></tr>
<tr><td>Study Animals</td><td>SPF birds divided into 3 groups

Group 1 vaccinated and challenged
Group 4 sham vaccinated and challenged (control)
Group 5 sham vaccinated and sham-challenged (negative control)</td></tr>
<tr><td>Challenge Description</td><td>IBDV variant E challenge administered at 33 days of age</td></tr>
<tr><td>Interval observed after challenge</td><td>Observed daily for 11 days post challenge and body weights and bursal weights collected. Sex of birds was recorded.</td></tr>
<tr><td>Results</td><td>The body weight and bursal weight were collected and B/B weight ratio (bursa weight/body weight ratio) was calculated for each bird and compared between the challenged groups: vaccinates (Group 1) and placebo controls (Group 4).

Table 1
<table>
<tr><td>Group</td><td># birds</td><td>Min</td><td>Q1</td><td>Med</td><td>Q3</td><td>Max</td></tr>
<tr><td>1</td><td>30</td><td>0.12</td><td>0.19</td><td>0.26</td><td>0.43</td><td>0.71</td></tr>
<tr><td>4</td><td>30</td><td>0.08</td><td>0.11</td><td>0.14</td><td>0.15</td><td>0.20</td></tr>
<tr><td>5</td><td>30</td><td>0.34</td><td>0.48</td><td>0.62</td><td>0.72</td><td>0.93</td></tr>
</table>
Table 2
<table>
<tr><td>Gender</td><td>Group</td><td>Min</td><td>Q1</td><td>Med</td><td>Q3</td><td>Max</td></tr>
<tr><td>Female</td><td>1</td><td>0.14</td><td>0.18</td><td>0.28</td><td>0.47</td><td>0.65</td></tr>
<tr><td></td><td>4</td><td>0.08</td><td>0.11</td><td>0.13</td><td>0.16</td><td>0.2</td></tr>
<tr><td>Male</td><td>1</td><td>0.12</td><td>0.19</td><td>0.24</td><td>0.29</td><td>0.71</td></tr>
<tr><td></td><td>4</td><td>0.09</td><td>0.13</td><td>0.14</td><td>0.15</td><td>0.2</td></tr>
</table>
Min is minimum
Q is quartile
Med is Median
Max is maximum

Raw data on attached page</td></tr>
<tr><td>USDA Approval Date</td><td>December 8, 2017</td></tr>
</table>

Raw data shown below.

Group	ID	Sex (M=male, F=female)	Body_Weight (g)	Bursa_Weight (g)
1	343	M	522	1.01
1	356	F	448	2.91
1	358	F	536	2.76
1	364	M	591	0.73
1	366	F	410	0.72
1	372	M	581	1.71
1	379	F	471	0.68
1	385	M	548	1.21
1	388	F	560	2.76
1	390	M	515	1.04
1	393	F	460	2.13
1	396	F	536	0.82
1	397	F	451	0.83
1	408	M	609	3.18
1	415	M	787	1.42
1	418	M	533	1.33
1	419	F	442	2.14
1	432	M	514	1.41
1	433	M	554	1.25
1	440	F	487	2.1
1	442	F	523	1.49
1	443	M	559	1.06
1	444	M	661	4.68
1	453	M	608	1.8
1	455	F	552	1.67
1	459	F	540	0.82
1	465	F	510	1.44
1	470	F	506	1.01
1	471	F	576	1.09
1	473	M	610	1.65
4	341	M	619	0.88
4	344	F	523	0.72
4	349	F	483	0.8
4	355	F	484	0.56
4	357	F	533	0.74
4	361	F	494	0.98
4	365	F	499	0.57
4	368	F	464	0.5

4	375	M	485	0.95
4	380	F	435	0.46
4	387	M	600	0.88
4	389	M	532	0.82
4	391	M	577	0.83
4	394	M	540	0.57
4	404	F	473	0.77
4	405	M	565	0.89
4	421	M	556	0.71
4	429	F	498	0.64
4	430	M	545	0.82
4	436	M	613	0.54
4	439	M	539	0.72
4	441	M	509	0.73
4	448	F	420	0.7
4	461	M	606	0.89
4	462	M	552	0.56
4	463	M	568	0.89
4	464	F	486	0.38
4	475	M	586	0.71
4	482	M	605	0.91
4	485	F	487	0.56
5	346	M	656	3.68
5	351	F	460	2.09
5	352	M	695	2.37
5	359	F	463	3.18
5	376	M	568	5.29
5	384	M	515	2.38
5	392	F	496	1.75
5	399	M	626	3.52
5	414	M	587	4.52
5	416	M	580	2.67
5	417	M	490	4.46
5	420	M	671	3.52
5	422	M	575	5.17
5	425	M	649	5.3
5	435	F	486	2.97
5	438	M	673	5.18
5	446	M	681	3.65
5	447	M	692	4.19
5	450	M	622	4.5

5	452	F	496	2.27
5	457	F	491	3.09
5	466	M	692	2.87
5	469	M	637	3.03
5	476	M	635	3.94
5	478	M	558	3.26
5	479	M	574	5.06
5	480	M	639	4.03
5	481	M	597	3.9
5	487	F	489	3.51
5	488	M	625	4.41

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<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Bursal disease virus variant E</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate efficacy against bursal disease variant E</td></tr>
<tr><td>Product Administration</td><td>One dose administered in ovo route</td></tr>
<tr><td>Study Animals</td><td>SPF eggs at 18-19 days of embryonation divided into 3 groups:

Group 1 vaccinated with product and challenged
Group 5 sham vaccinated and challenged (control/placebo)
Group 6 sham vaccinated and sham-challenged (negative control)</td></tr>
<tr><td>Challenge Description</td><td>IBDV variant E challenge administered at 29 days of age (study day 31)</td></tr>
<tr><td>Interval observed after challenge</td><td>Observed daily for 11 days post challenge and body weights and bursal weights collected. Sex of birds was recorded.</td></tr>
<tr><td>Results</td><td>The body weight and bursal weight were collected and B/B wt. ratio (bursa weight/body weight ratio) was calculated for each bird and compared between vaccinates (Group 1) and challenge controls/placebos (Group 5).
Table 1
<table>
<tr><td>Group</td><td># birds</td><td>Min</td><td>Q1</td><td>Med</td><td>Q3</td><td>Max</td></tr>
<tr><td>1</td><td>30</td><td>0.12</td><td>0.32</td><td>0.43</td><td>0.52</td><td>0.75</td></tr>
<tr><td>5</td><td>30</td><td>0.11</td><td>0.12</td><td>0.14</td><td>0.18</td><td>0.22</td></tr>
<tr><td>6</td><td>30</td><td>0.34</td><td>0.43</td><td>0.49</td><td>0.53</td><td>0.72</td></tr>
</table>
Table 2
<table>
<tr><td>Gender</td><td>Group</td><td>Min</td><td>Q1</td><td>Med</td><td>Q3</td><td>Max</td></tr>
<tr><td>Female</td><td>1</td><td>0.12</td><td>0.37</td><td>0.49</td><td>0.52</td><td>0.68</td></tr>
<tr><td></td><td>5</td><td>0.11</td><td>0.12</td><td>0.14</td><td>0.17</td><td>0.21</td></tr>
<tr><td>Male</td><td>1</td><td>0.12</td><td>0.31</td><td>0.42</td><td>0.58</td><td>0.75</td></tr>
<tr><td></td><td>5</td><td>0.12</td><td>0.14</td><td>0.15</td><td>0.17</td><td>0.22</td></tr>
</table>
Min is minimum
Q is quartile
Med is Median
Max is maximum

Raw data on attached page</td></tr>
<tr><td>USDA Approval Date</td><td>January 26, 2018</td></tr>
</table>

Raw data shown below.

Group	ID	Sex (M=male, F=female)	Body_Weight (g)	Bursa_Weight (g)
1	731	M	497	0.58
1	734	M	452	0.76
1	737	M	499	1.68
1	755	F	461	1.93
1	766	M	486	3.64
1	775	M	544	3.61
1	793	M	510	2.09
1	808	M	516	2.08
1	809	M	482	3.51
1	812	M	514	2.42
1	822	M	574	1.71
1	826	M	568	3.76
1	830	F	425	2.23
1	831	M	590	2.82
1	833	F	434	1.6
1	838	F	416	2.34
1	845	F	470	0.85
1	847	M	531	2.25
1	850	M	464	2
1	851	M	444	0.67
1	858	F	395	2.67
1	863	F	487	2.48
1	866	F	426	2.07
1	867	F	499	1.89
1	882	M	470	2.34
1	888	F	385	0.45
1	889	M	552	1.75
1	890	F	451	2.28
1	903	M	391	0.9
1	908	M	534	3.78
5	732	M	488	0.91
5	738	M	521	0.7
5	743	M	423	0.63
5	748	F	456	0.59
5	750	F	384	0.79
5	754	F	380	0.69
5	757	F	467	0.7

5	758	F	425	0.53
5	762	F	456	0.51
5	765	M	508	0.61
5	776	M	512	0.9
5	778	F	450	0.89
5	782	F	445	0.48
5	784	M	508	1.12
5	791	M	481	0.7
5	800	F	369	0.57
5	806	M	509	0.66
5	807	F	378	0.53
5	810	F	406	0.74
5	811	M	397	0.54
5	815	F	396	0.57
5	825	M	500	0.89
5	828	F	447	0.54
5	832	M	507	0.73
5	843	M	495	0.83
5	871	F	423	0.48
5	872	M	538	0.78
5	881	M	416	0.62
5	894	F	387	0.45
5	906	M	505	0.61
6	744	M	580	2.39
6	747	F	478	2.39
6	749	F	441	2.69
6	772	F	454	2.13
6	779	F	442	2.37
6	795	F	480	2.56
6	797	M	530	1.82
6	804	F	414	1.8
6	805	F	463	1.8
6	816	M	485	2.41
6	829	M	531	2.25
6	835	M	588	2.09
6	844	F	427	2.02
6	848	F	483	2.51
6	856	M	501	1.99
6	859	M	516	3.39
6	862	M	487	2.39
6	865	M	539	2.36

6	868	F	430	1.97
6	874	F	404	2.05
6	878	M	515	1.86
6	883	F	426	1.88
6	884	M	456	2.49
6	892	M	495	3.01
6	893	F	471	2.32
6	896	M	477	2.11
6	897	F	478	3.22
6	901	F	445	3.2
6	905	M	476	2.4
6	910	M	595	2.98

Study Type	Efficacy
Pertaining to	Marek's disease virus
Study Purpose	Demonstrate efficacy against virulent Marek's disease
Product Administration	One dose administered subcutaneous route
Study Animals	SPF day-old chicks divided into groups Group 4: Vaccinated with product and challenged Group 5: Sham vaccinated and challenged (positive controls) Group 6: Sham vaccinated and sham-challenged (negative controls)
Challenge Description	Serotype-1 (SR-1) GA 22 strain
Interval observed after challenge	The birds were observed daily for clinical signs for 7 weeks.
Results	Vaccinates and controls were evaluated in terms of Marek's disease clinical signs and/or grossly observable lesions per the criteria in 9 CFR 113.330(c)(4) & (5). Birds with clinical signs and/or observable lesions: Group 4: 6/35 Group 5: 34/35 Group 6: 0/34 Requirements of 9 CFR 113.330(c)(4) & (5) were met. Raw data on attached page.
USDA Approval Date	January 25, 2018

Raw data shown below for birds classified as positive. All other birds normal.

Group/Bird	Paralysis	Locomotive Signs	Emaciation	Depression	Liver	Spleen	Heart	Muscle	Gonads	Kidneys	Other Gross Lesions	Comments
4/1					X	X		X	X	X		
4/2								X				
4/3		X				X				X		
4/4		X				X						
4/5		X				X				X		
4/6					X	X				X		
5/1				X	X			X		X		
5/2				X		X				X		
5/3				X		X						
5/4		X				X						
5/5		X				X						
5/6	X		X			X				X		
5/7			X	X	X	X				X		
5/8				X		X						
5/9		X				X				X		
5/10				X		X						
5/11				X		X					X	Gross Lesions: Skin
5/12				X		X				X		
5/13			X	X							X	Gross Lesions: Skin
5/14			X	X	X	X				X		
5/15			X	X	X	X				X		
5/16				X		X				X	X	Gross Lesions: Skin
5/17				X	X	X				X		
5/18										X		
5/19				X		X				X		
5/20				X		X				X		
5/21						X	X					
5/22			X	X	X	X	X			X		
5/23		X		X		X				X		
5/24			X	X		X				X		
5/25		X				X	X			X		
5/26		X						X		X		
5/27				X		X				X		
5/28				X			X			X		
5/29		X			X	X	X			X		
5/30						X			X	X		

Group/Bird	Paralysis	Locomotive Signs	Emaciation	Depression	Liver	Spleen	Heart	Muscle	Gonads	Kidneys	Other Gross Lesions	Comments
5/31				X	X	X				X		
5/32		X			X					X		
5/33				X		X				X		
5/34				X	X		X			X		

Study Type	Efficacy
Pertaining to	Marek's Disease virus
Study Purpose	Demonstrate efficacy against Marek's disease
Product Administration	One dose administered *in ovo* route
Study Animals	SPF eggs divided into groups Group 1: Vaccinated with product and challenged Group 2: Sham vaccinated and challenged (positive controls) Group 3: Sham vaccinated and sham challenged (negative controls)
Challenge Description	Serotype-1 (SR-1) GA 22 strain at 4 to 5 days-of-age
Interval observed after challenge	The birds were observed daily for clinical signs for 7 weeks.
Results	Vaccinates and controls were evaluated in terms of Marek's grossly observable lesions per the criteria in 9 CFR 113.330(c)(4) & (5). Birds with clinical signs and/or observable lesions: Group 1: 5/34 Group 2: 32/33 Group 3: 0/35 Requirements of 9 CFR 113.330(c)(4) & (5) were met. Raw data on attached page.
USDA Approval Date	February 13, 2018

Raw data shown below for birds classified as positive. All other birds normal.

Group/ Bird	liver	spleen	heart	muscle	gonads	kidneys	other gross lesions	comments
1/1	X	X						
1/2		X						
1/3					X	X		
1/4	X	X						
1/5				X	X			
2/1	X	X				X		
2/2		X						
2/3	X	X		X				
2/4	X	X		X	X	X	X	Skin
2/5	X	X					X	Skin
2/6	X	X	X		X	X	X	Skin
2/7	X	X					X	Skin
2/8		X						
2/9	X	X						
2/10	X	X					X	Skin
2/11	X	X	X					
2/12	X	X						
2/13	X	X						
2/14	X	X				X		
2/15		X	X					
2/16	X	X					X	Skin
2/17	X	X				X		
2/18	X	X				X		
2/19	X	X						
2/20		X						
2/21			X			X		
2/22	X	X	X			X		
2/23		X						
2/24		X						
2/25		X						
2/26		X				X		
2/27		X						
2/28		X				X		
2/29	X	X						
2/30		X						
2/31		X						
2/32		X				X		

Study Type	Efficacy
Pertaining to	Newcastle disease virus (NDV)
Study Purpose	Demonstrate efficacy against NDV
Product Administration	One dose administered *in ovo* at 18-19 days of embryonation
Study Animals	SPF eggs divided into 2 groups Group 2 vaccinated with Code 1A89.R1 and challenged Group 5 placebo vaccinated and challenged (control)
Challenge Description	NDV Texas GB challenge administered at 28 days post vaccination
Interval observed after challenge	Observed daily for 14 days for clinical signs of NDV, particularly nervous or respiratory clinical signs, including death
Results	Vaccinates and controls were evaluated in terms of Newcastle disease per the criteria in 9 CFR 113.329(c). Birds with NDV clinical signs: Group 4: 2/30 Group 5: 30/30 Requirements of 9 CFR 113.329(c) were met. Raw data on attached page
USDA Approval Date	September 7, 2017

Raw data shown below for birds classified as positive. All other birds normal.

Group/Bird	Death	NDV Result
4/1	x	Positive
4/2	x	Positive
5/1	x	Positive
5/2	x	Positive
5/3	x	Positive
5/4	x	Positive
5/5	x	Positive
5/6	x	Positive
5/7	x	Positive
5/8	x	Positive
5/9	x	Positive
5/10	x	Positive
5/11	x	Positive
5/12	x	Positive
5/13	x	Positive
5/14	x	Positive
5/15	x	Positive
5/16	x	Positive
5/17	x	Positive
5/18	x	Positive
5/19	x	Positive
5/20	x	Positive
5/21	x	Positive
5/22	x	Positive
5/23	x	Positive
5/24	x	Positive
5/25	x	Positive
5/26	x	Positive
5/27	x	Positive
5/28	x	Positive
5/29	x	Positive
5/30	x	Positive

Study Type	Efficacy
Pertaining to	Newcastle disease virus (NDV)
Study Purpose	Demonstrate efficacy against NDV
Product Administration	One dose administered subcutaneously
Study Animals	SPF chicks, one day of age, divided into 2 groups Group 1 vaccinated with Code 1A89.R1 and challenged Group 4 sham vaccinated and challenged (control)
Challenge Description	NDV Texas GB challenge administered at 28 days post vaccination
Interval observed after challenge	Observed daily for 14 days for clinical signs
Results	Vaccinates and controls were evaluated in terms of Newcastle disease per the criteria in 9 CFR 113.329(c). Birds with NDV clinical signs: Group 1: 3/30 Group 4: 30/30 Requirements of 9 CFR 113.329(c) were met. Raw data on attached page
USDA Approval Date	January 11, 2018

Raw data shown below for birds classified as positive. All other birds normal.

Group/Bird	Paralysis	Death	NDV Result
1/1		X	Positive
1/2	X		Positive
1/3		X	Positive
4/1		X	Positive
4/2		X	Positive
4/3		X	Positive
4/4		X	Positive
4/5		X	Positive
4/6		X	Positive
4/7		X	Positive
4/8		X	Positive
4/9		X	Positive
4/10		X	Positive
4/11		X	Positive
4/12		X	Positive
4/13		X	Positive
4/14		X	Positive
4/15		X	Positive
4/16		X	Positive
4/17		X	Positive
4/18		X	Positive
4/19		X	Positive
4/20		X	Positive
4/21		X	Positive
4/22		X	Positive
4/23		X	Positive
4/24		X	Positive
4/25		X	Positive
4/26		X	Positive
4/27		X	Positive
4/28		X	Positive
4/29		X	Positive
4/30		X	Positive

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>ALL</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate safety of product under typical use conditions</td></tr>
<tr><td>Product Administration</td><td>1 dose by either the in ovo or subcutaneous route</td></tr>
<tr><td>Study Animals</td><td>Commercial chicken eggs at 18 to 19 days of embryonation or chickens at one day of age. At each of the three sites, one group received the test vaccine and one group received vaccinations according to site standard practices. Hatchability for in ovo vaccinated groups was recorded. Animals were observed daily for mortality for 21 days.</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>Not applicable</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th>Location</th><th>Treatment</th><th>Total Placed</th><th>21 Day Mortality</th><th>% Mortality</th><th>% Hatchability</th></tr>
<tr><td>1</td><td>In ovo</td><td>28,100</td><td>669</td><td>2.4</td><td>87.6</td></tr>
<tr><td>1</td><td>Control</td><td>28,100</td><td>490</td><td>1.7</td><td>88.8</td></tr>
<tr><td>2</td><td>In ovo</td><td>27,800</td><td>456</td><td>1.6</td><td>89.3</td></tr>
<tr><td>2</td><td>Control</td><td>27,800</td><td>494</td><td>1.8</td><td>89.8</td></tr>
<tr><td>3</td><td>SQ</td><td>31,015</td><td>646</td><td>2.1</td><td>N/A</td></tr>
<tr><td>3</td><td>Control</td><td>31,022</td><td>789</td><td>2.5</td><td>N/A</td></tr>
</table>
N/A = not applicable

No adverse reactions attributable to the vaccine were recorded.
</td></tr>
<tr><td>USDA Approval Date</td><td>July 16, 2019</td></tr>
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