



United States Department of Agriculture



CVB UPDATE FOR USAHA

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ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES
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Staffing & Budget



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CVB Budget Comparison

FY 2015

Vet Biologics Enacted - \$16.4

VS Vet Biologics Approp - \$13.3M

CVB Allocation - \$18.8M

- Vet Biologics Line - \$12M
- Commodity Lines - \$3.6M
- IT & Other Misc Lines - \$2.4M
- Supplemental (H1N1/HPAI) - \$871K

FY 2016

Vet Biologics Enacted - \$16.4

VS Vet Biologics Approp - \$14.1M

CVB Allocation - \$19.3M

- Vet Biologics Line - \$12.4M
- Commodity Lines - \$3.5M
- IT & Other Misc Lines - \$2.4M
- Supplemental (H1N1/HPAI) - \$1M



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CVB Budget Comparison

FY 15 ≈ FY 16 ≈ FY 17 ≈ FY 18



CVB Staffing Comparison

FY 2015 STAFFING

Total Program Staffing – 106

- PEL – 66
- IC – 23
- Admin/Other – 17

Total Program Vacancies - 21

NCAH Shared Staffing – 257

NCAH Vacancies - 44

FY 2016 STAFFING

Total Program Staffing – 107

- PEL – 67
- IC – 23
- Admin/Other – 17

Total Program Vacancies - 22

NCAH Shared Staffing – 259

NCAH Vacancies - 55



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Single-tier label rule



New labeling regulations

- APHIS rule 2011-0049: simplifies effectiveness claims on labeling and requires publication of efficacy/safety data at productdata.aphis.usda.gov
- APHIS rule 2008-0008: provides numerous changes to label content, disclosures

Co-implementation beginning October 31, 2016

- Newly licensed products will comply immediately
- Previously licensed products phased in over 4-year period



Scope of Products Affected

Single Label Claim

- Vaccines, bacterins, toxoids, immunomodulators
- NOT diagnostics, antibody products, allergenic extracts

Labeling and Packaging

- All domestically marketed biologics



Simplified labeling format

Previously:

This product is indicated for the prevention of disease against Virus A, as an aid in the control of respiratory disease due to Virus B, an aid in the prevention of infection with Virus C, and an aid in the prevention of enteric disease due to Virus B.

Now:

This product is effective against Virus A, Virus C, and respiratory and enteric disease due to Virus B. See productdata.aphis.usda.gov for efficacy and safety data.



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productdata.aphis.usda.gov

(note: no “www”)

Search engine to find desired products by:

- Trade Name
- True Name
- Manufacturer
- Distributor
- USDA Product Code
- Animal species for use

The screenshot shows the USDA website header with the logo and navigation links. The main content area is titled 'Licensed Veterinary Biological Product Information' and includes a search bar, a 'Print' button, and a list of currently licensed products. A note indicates that product licensing efficacy or safety data may be limited due to phased implementation of regulation. A 'Precautionary Statements and Disclaimers' section follows, stating that conclusions regarding vaccine effectiveness should not be based on these data summaries. The page also includes a 'Newly Published Information' section at the bottom.

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Veterinary Accreditation
Veterinary Biologics
About CVB
Newly Published Information

Licensed Veterinary Biological Product Information

Last Modified: Sep 23, 2016 [Print](#)

Currently Licensed Veterinary Biological Products (includes imported under permit)

[Current Veterinary Biologics Product Catalogue \(July 6, 2016\)](#)

[Currently Licensed Biologics for Aquatic Animals \(August 30, 2016\)](#)

Product Licensing Data

The purpose of these web pages is to improve the way information is provided to the general public, and the veterinary community, regarding product performance by providing efficacy and safety data used to license the product. These web pages do not apply to diagnostic test kits, allergenic extracts, antibody products or autogenous products.

NOTE: *There may be limited product licensing efficacy or safety data available on this website due to the phased implementation of this regulation. Products will be phased in over a period of 4 years.*

Precautionary Statements and Disclaimers

Conclusions regarding how effective or safe a vaccine is compared to a similar vaccine should not be made on the basis of these data summaries. Differences in animals and study design may vary too much for meaningful comparisons to other vaccines.

Please consult with a licensed veterinarian for interpretation of data.



Product Compilation Summary

- Posted to productdata.aphis.usda.gov
- Contains each efficacy and safety study used to support licensure of a single product
- Studies may be added if product approved for additional claims after initial licensure



Summary of Studies Supporting USDA Product Licensure

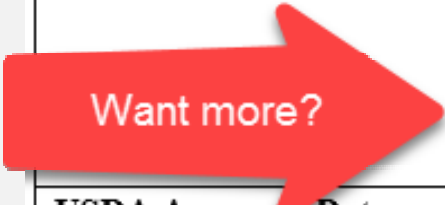
Establishment Name	Great Vaccine Company	
USDA Vet Biologics Establishment Number	000	
Product Code	49K5.XX	
True Name	Porcine Circovirus Vaccine, Killed Virus, Mycoplasma Hyopneumoniae Bacterin	
Trade Name(s)/Distributor (if different from manufacturer)	Tradename PigVacc Plus OinkVacc	Distributor ABC Distributing
Date of Compilation Summary	November 13, 2015	

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.



Individual Study Summaries on subsequent pages

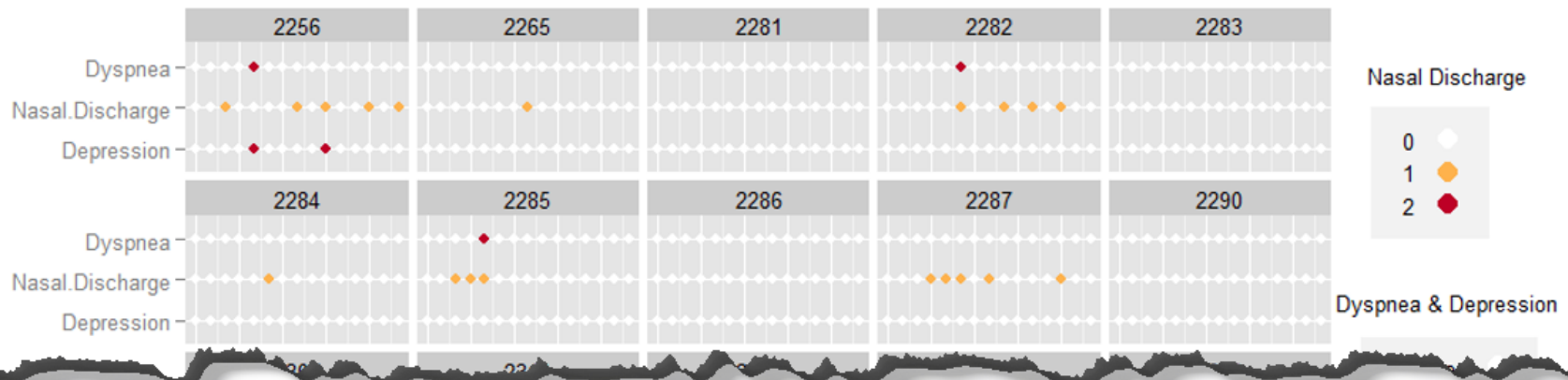
Study Type	Efficacy
Pertaining to	<u>Herpesvirus</u> , bovine (IBR)
Study Purpose	Demonstrate effectiveness against infectious bovine <u>rhinotracheitis</u>
Product Administration	Single dose, administered subcutaneously
Study Animals	Forty calves, <u>seronegative</u> to IBR, 3 months of age, 20 vaccinates and 20 controls
Challenge Description	IBR virus administered 14 days after vaccination
Interval observed after challenge	Calves observed daily for 14 days after challenge
Results	<p>Animals were considered affected by the challenge if they had a temperature ≥ 104.0 on more than one day AND demonstrated at least one clinical sign (depression, dyspnea, or purulent nasal discharge) on at least one day.</p> <p>Totals: 16/18 controls affected 0/17 vaccinates affected</p> <p>Raw data: See attached.</p>
USDA Approval Date	mm/dd/yyyy





		Rectal Temperatures																
Controls																		
Calf	Day 62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	Classification	
2245	101.9	101.2	101.2	102.2	104.8	104.5	104.7	102.5	103.1	104.1	101.2	100.7	100.5	102	101.3	101	Positive	
2267	101.2	101.6	101.7	104.6	104.9	103.1	104	103.2	101.6	101	101.6	100.3	100.9	100.6	101	100.4	Positive	
2273	101.9	101.5	101.9	103.6	105	104.9	104.9	103	101.6	101.8	100.7	101.7	101.1	101.1	101	100.9	Positive	
2274	101.3	101.9	101.2	103.1	103.5	106.2	105.4	104.2	101	103.9	101.2	101.8	101.2	101.1	101	102.6	Positive	
2291	101.8	101	101.4	103.3	104.2	104.6	104	103	102.3	101.7	100.6	101.5	100.8	101.1	101.2	100.4	Positive	
2298	101.2	102.7	102	102.3	103.4	104	104	102.4	103.5	102.7	101.9	101	101.2	101.6	101.4	101.8	Positive	
2302	101.4	101.4	101.6	101.6	102	103.8	103.7	103.3	102	101.5	101.5	101.2	100.7	101.6	101.6	101.7	Negative	
10	101	101	101.7	104	103.3	105.4	104	103.7	103.3	104.1	100.5	101.5	100	101.7	101	101	Positi	

Vaccinates



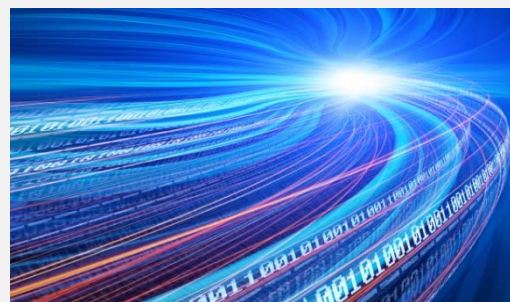


Additional labeling changes

- Revaccination statements—must be based on data, no default to yearly
- Reproductive safety—must state whether product has been evaluated in pregnant animals
- Additions:
 - Veterinary Biologics Product Code
 - Consumer contact telephone
 - All preservatives, not just antibiotics



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NCAH Portal

Web-based submissions



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Features of NCAH Portal

- Access based on level 2 USDA e-authorization credentials
- Entirely paperless
- Customer entry based on familiar APHIS forms
- Can upload a variety of supporting documents
- Interacts directly with CVB's database and internal routing system (LSRTIS)



Example Portal Entry

Submission Type	Report		
Submission Subtype(s)	• Efficacy-pivotal or DOI		
Tag(s)	None Entered		
Brief Description	efficacy report 3129B showing protection against neonatal colibacillosis		
Direct Submission To	Clough, Nancy		
Also Notify (cc)	None Entered		
Related Submissions	None Entered		
Submitted Files	File	Type	Submitter's Study ID Date Added ▼
	MyStatFile2.csv	Incoming statistical data files	08/16/2016
	test_ver2.docx	Incoming submission (core)	3127B 08/16/2016
	Test2.docx	Incoming submission (core)	3127B 08/16/2016
	MyStatFile1.csv	Incoming statistical data files	08/16/2016
Superseded Files	File	Type	Submitter's Study ID Date Added ▼
	test.docx	Incoming submission (core)	3127B 08/16/2016



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Example Portal Entry, Cont'd

CVB Response Files

File

Type

[999CVBResponseLetter.pdf](#)

Outgoing Correspondence

Submission History

Action	Timestamp	User	Info
Submission Entered	Aug-16-2016 09:54 AM CDT	Smith, Janie	
Submission Updated	Aug-16-2016 09:57 AM CDT	Smith, Janie	Attachments added
Submission Updated	Aug-16-2016 10:00 AM CDT	Smith, Janie	Attachments added
Submitted To CVB	Aug-16-2016 10:02 AM CDT	Smith, Janie	ML# 176467
Submission Updated	Aug-16-2016 10:07 AM CDT	Smith, Janie	Attachments appended
Submission Status Updated	Aug-16-2016 10:27 AM CDT		Completed



Efficiencies of NCAH Portal

- Time and cost savings printing/mailing submissions and regulatory responses
- Maintains a complete list of pending submissions for each establishment, with current review status
- Simultaneous access to the same information for every authorized user at an establishment
- Facilitates team assembly of submissions—each can upload their contribution to a draft submission.



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Other items



NIES Risk Assessment

- Set back a year due to HPAI
- Initial draft commented on
- Still being worked on, but not finished

Pharmacovigilance Final Rule

- Proposed rule published Fall of 2015
- All comments addressed
- Signed off though Dept.

NEPA Implementing Rule Revision

- Proposed rule published
- Not as many comments as expected
- CVB's have been responded to
- Not sure when final may be published
- Important implications



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Questions?????



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