USDA
United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE 18-13

TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Leadership Team

FROM: Byron Rippke
Director

BYRON RIPPKE
Digitally signed by BYRON RIPPKE
Date: 2018.11.29 13:31:18 -06'00'

SUBJECT: Labeling of Vaccines Containing Porcine Circovirus Type 2

I. PURPOSE

This notice informs licensees, permittees, and applicants of the current Center for Veterinary Biologics (CVB) policy concerning disclosure of Porcine Circovirus Type 2 genotypes used in vaccines and efficacy challenges.

II. BACKGROUND

Porcine Circoviruses are small non-enveloped circular ssDNA viruses of the genus *Circovirus* and family *Circoviridae*. Porcine Circovirus Type 1 (PCV1) is considered non-pathogenic, whereas Porcine Circovirus Type 2 (PCV2) causes a complex of porcine circovirus-associated diseases (PCVAD) in pigs. PCV2 is divided into at least six genotypes, PCV2a through PCV2f, as a result of genotype shifts in the ORF2 genome.[1,2] Although PCV2a was previously considered to be the most prominent, recent publications from 2003 onward, have reported that PCV2b and PCV2d seem to be more virulent and are prominently circulating in pigs[2]. In addition, there appears to be partial cross-protection among some currently identified PCV2 genotypes.

Due to the emergence of new PCV2 genotypes and their impact on vaccine effectiveness, the CVB has determined that it is appropriate to disclose genotype information on product labeling.

[1] Brendan, D., Wang, X., Dvorak, C. M. T., Marthaler, D., and Murtaugh, M. 2017, Virus Research 217: 32-37.[2]
[2] Karuppannan, A. K., and Opriessnig, T. 2017, Viruses 9: 99; doi: 10.3390/v9050099

III. ACTION (or POLICY)

All labels and Section VI of the Outlines of Production for products containing PCV2 should state the genotype(s) of PCV contained in the product (e.g. PCV2a, PCV2b, PCV2d, etc.), as described in Veterinary Services Memorandum (VSM) 800.54, Section III.H. Likewise, in the Individual Study Summaries (ISS)s firms must specify the genotype(s) of PCV for which efficacy has been demonstrated by including the genotype of challenge viruses used in approved pivotal efficacy studies. A general single tier claim will be allowed for any licensed product, e.g.:
"This product has been shown to be be effective for the vaccination of healthy pigs X days of age or older against Porcine Circorvirus 2."

Alternatively, specific claims for genotypes against which efficacy has been individually demonstrated will also be allowed, e.g.:
"This product has been shown to be be effective for the vaccination of healthy pigs X days of age or older against Porcine Circorvirus 2a, 2b, and 2d."

IV. IMPLEMENTATION/ APPLICABILITY

The CVB is requiring that firms amend the Outlines of Production, labels, and ISSs for previously licensed products within one year from the date of this Notice. The CVB will update the related Product Compilation Summaries (PCS)s accordingly. Firms must disclose PCV genotypes contained in the vaccine on labels and in Outlines, and disclose the genotype of challenge strains used to demonstrate efficacy in ISSs, so the CVB can generate the appropriate PCSs.