



September 16, 2005

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Dr. Richard E. Hill, Jr.  
Director  
Center for Veterinary Biologics (CVB)  
United States Department of Agriculture  
Animal and Plant Health Inspection Service  
Veterinary Services  
510 S. 17<sup>th</sup> Street, Suite 104  
Ames, IA 50010

**Re: Center for Veterinary Biologics Notice No. Draft-007,  
Type (Species) Designation of Vaccines Containing Bovine Viral Diarrhea Virus(es)**

Dear Dr. Hill,

I am writing on behalf of the American Veterinary Medical Association (AVMA), established in 1863 and the largest veterinary medical association in the world. As a not-for-profit association established to advance the science and art of veterinary medicine, AVMA is the recognized national voice for the veterinary profession. The association's more than 72,000 members represent approximately 86% of U.S. veterinarians, all of whom are involved in myriad areas of veterinary medical practice including private, corporate, academic, industrial, governmental, military, and public health services.

Draft Notice No. 007 proposes that Bovine Viral Diarrhea Virus (BVDV) vaccine labels include the vaccine BVDV Type(s) in the indications statement and the Type of the BVDV challenge virus for which efficacy has been demonstrated as part of the product claim.

We recognize irregularities exist among BVDV vaccine labels. Some bear historic labels, some imply they cross protect against types, some make type distinctions, and others do not make distinctions. This is confusing and potentially misleading to vaccine users. We see value in making label terminology more uniform and "leveling the playing field."

In principle, the AVMA is very pleased with the CVB's attempt to provide additional science-based information on biologic labels to help veterinarians have a clearer expectation of product performance. We believe strongly in such initiatives, including the anticipated provision of pivotal safety and efficacy summaries for biologic products. We urge CVB to apply the concept of clarifying vaccine content and challenge agent to other vaccine products.

However, we believe the diversity of BVDV and the accompanying variability in biologic protection poses significant challenges. BVDV typing is based on genetics and not immune response. As proposed, the CVB draft could cause BVDV labels to be potentially false or misleading because the approach oversimplifies the dynamics of BVDV protection. Because of the diversity of BVDV, a type 2 vaccine may or may not

protect against all type 2 infections and may also protect against a type 1 infection even if the product is not labeled as such. For example, a type 2 challenge virus label would imply that the vaccine would protect against all type 2 viruses and it may not. This gives a false sense of security to the end user and undermines the very goal of communicating an accurate expectation of product performance.

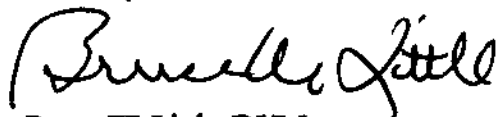
Fortunately, we believe we have a way to address this conundrum. The AVMA strongly recommends that, specific to BVDV, a sentence must be included on labels to inform the end-user that a challenge based strictly on BVDV typing alone does not imply protection against all BVDV subtypes in the field.

The AVMA believes in the concept of typing challenge virus and assuring that the challenge virus is heterologous. This is a step in the right direction and we encourage CVB to apply the concepts to other viral vaccines.

**In summary, the AVMA supports the CVB proposal with the requirement that a sentence be added to BVDV labels to inform the end-user that a challenge based strictly on BVDV typing alone does not imply protection against all BVDV subtypes in the field.**

Biologic labeling significantly impacts veterinarians and the animals under their care. Thank you for this opportunity to comment.

Sincerely,



Bruce W. Little, DVM  
Executive Vice President

BWL/ECG