



March 1, 2006

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 06-06

Animal and Plant
Health Inspection
Service

Subject: Type (Species) Designation of Vaccines Containing
Bovine Viral Diarrhea Virus(es)

Veterinary Services

Center for Veterinary
Biologics

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics
Area Veterinarians in Charge, VS
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I. PURPOSE

This notice informs licensees, permittees, and applicants of current Center for Veterinary Biologics (CVB) guidance for label disclosure of Bovine Viral Diarrhea (BVD) Virus Type (species) used in vaccines and challenge studies.

II. BACKGROUND

Historically, BVD viruses (BVDV) were considered to be a single species within the pestivirus genus of the flavivirus family of viruses. Accordingly, the CVB did not require that BVDV type be specified on product labels or in the Outline of Production, although firms were allowed to provide that information voluntarily. Similarly, the CVB did not require that firms disclose to the consumer the type of BVD used in challenge studies to demonstrate vaccine efficacy.

The International Committee on Taxonomy of Viruses has recently designated BVDV Types 1 and 2 as separate species within the pestivirus genus.¹ Their findings are that BVDV Type 1 and 2 are genetically distinct, based primarily on nucleotide sequence and serological relatedness. Current literature and taxonomy conventions now designate these distinct viruses as BVDV Type 1 and BVDV Type 2. Given the status of taxonomic classification and scientific literature, the CVB has reviewed policy regarding the use of Type designations for BVD products, and has determined that it is appropriate for this information to be included on product labeling and in Outlines of Production.

III. GUIDANCE

The CVB is not considering changing the True Names of BVD-containing products. However, the BVDV Type(s) included in the product should be disclosed on the label as part of the indications statement. In addition, the label should indicate, as part of the product claim, the Type of the BVD challenge virus for which efficacy has been demonstrated.



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Example:

“This product contains BVD Type 1 and is recommended for the vaccination of healthy cattle as an aid in the control of disease caused by BVD Type X.”

In this example, “X” is the Type(s) of the BVD challenge strain used in the efficacy trial.

The BVD Type of the Master Seed and challenge strains should be determined by genetic sequencing of the 5' untranslated region (UTR), or by some other method acceptable to the CVB. The results of this characterization should be submitted to the CVB to support the label and Outline of Production.

If the challenge strain used in a previous efficacy study is no longer available, contact the CVB to discuss acceptable disclosure language on product labels.

IV. ACTION

For BVD-containing products, all labels and Section VI of the Outline of Production should be revised to include the Type(s) of BVDV contained in the product and to indicate the Type(s) of BVDV used for challenge in the efficacy trial. In addition, Section I of the Outline of Production should be amended to specify the Type of the BVDV Master Seed(s).

Previously approved Master Seeds that were not originally characterized to the species level (BVDV Type) should be sequenced in the 5' UTR or characterized by some other method acceptable to the CVB. Data confirming the Master Seed species should be submitted to the CVB along with label and Outline of Production changes. The CVB may perform confirmatory testing.

Characterization of Master Seeds and modifications to Outlines of Production and labels should be completed within 1 year from the date of this Notice.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics

¹ Heinz FX, Collett MS, Purcell RH, et al.: 2000, Genus pestivirus. In: Virus taxonomy, eds. van Regenmortel MHV, Fauquet CM, Bishop DHL, et al., pp. 867-872. Academic Press, New York.