



May 21, 2012

**CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 12-11**

**United States  
Department of  
Agriculture**

Animal and Plant  
Health Inspection  
Service

Veterinary Services

Center for Veterinary  
Biologics

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

**FROM:** Richard E. Hill, Jr. /s/ *Richard E. Hill, Jr.*  
Director  
Center for Veterinary Biologics

**SUBJECT:** Virulent Systemic Feline Calicivirus Label Claims

**I. PURPOSE**

The purpose of this notice is to clarify the Center for Veterinary Biologics' (CVB) policy regarding label claims implying protection against Virulent Systemic Feline Calicivirus (VS FCV), and the data required to support those claims.

**II. BACKGROUND**

In general, outbreaks of VS FCV are rare and have been self-limiting. The isolate from each outbreak appears genetically unique and seems to have appeared spontaneously, by mutation from caliciviruses already present in the affected cats (*Vet Clin Small Anim* 38:775-786). The expected degree of cross-protection against other virulent isolate(s) is unknown.

**III. POLICY**

The CVB has determined that label claims associated with VS FCV should be consistent with the studies conducted. Brief study summaries *may* be included on label inserts, final container labels, or final carton labels, but this is not required. Using a heterologous challenge strain is strongly recommended when conducting efficacy studies to support label claims associated with VS FCV. If the vaccination/challenge study is conducted with a strain homologous to a strain included in the vaccine strain, additional work should be done to assess serologic neutralizing activity against multiple VS FCV strains. Submitting a protocol for review prior to conducting these studies is strongly recommended.

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**IV. IMPLEMENTATION/ APPLICABILITY**

This policy will be effective immediately. It is expected that all labeling materials with claims associated with VS FCV will comply with this policy within 6 months of the date of this Notice.