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June 6, 2005

Dr. Richard E. Hill, Jr.  
Director  
Center for Veterinary Biologics  
510 South 17<sup>th</sup> Street  
Suite 104  
Ames, Iowa 50010

**Re: Center for Veterinary Biologics Notice No. Draft-004**  
**Label Requirements for the Products Under Conditional Licenses**

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 85% of U.S. veterinarians, all of whom are involved in the myriad areas of veterinary medical practice including private, corporate, academic, industrial, governmental, military, and public health services. The AVMA commends the Center for Veterinary Biologics for offering a proposal to differentiate labels of conditionally licensed products from labels of fully licensed products. This kind of effort is consistent with AVMA's emphasis on science-based labels that communicate an appropriate expectation of product performance.

CVB may grant a conditional license in order to meet an emergency condition, limited market, local situation, or other special circumstance. Since less is known about the efficacy and/or potency of conditionally licensed products than fully licensed products, it is appropriate that labeling identifies this lack of equivalence.

AVMA's comments on specific components of the proposed labeling notice for conditionally licensed products appear below.

**1. CVB proposes the following disclosure statement should be printed on the label:**

**"Notice! This product license is conditional. Efficacy and/or potency of this product have not been fully demonstrated."**

AVMA strongly supports the concept of a clear, consistent, label disclosure statement that explains the level of confidence one can have in the efficacy and/or potency of a conditionally licensed product.

In the past, we have heard conditionally licensed products described as having a “reasonable expectation of efficacy.” If true, the AVMA would suggest incorporating this helpful phrase into the CVB proposed phrase.

In addition, we urge that labels, perhaps via website, provide a summary of efficacy-related data used to support conditional licensure. The summary should identify efficacy-related results, including what outcomes were monitored and how outcomes were determined. It is important that this summary provides information that assists clinical decision-making.

It would also be helpful if labels communicated the safety assured by the conditional licensure process, including, perhaps via website, a summary of safety related data.

**2. The disclosure statement should appear in a prominent position on the label, preferably under the True Name of the product. The font size should be larger and bolder than the rest of the label text (except the True Name).**

The AVMA agrees the label statement should be prominent and easily read.

**3. A statement regarding revaccination, similar to the following, should be included:  
“Duration of immunity for this product has not been evaluated; consultation with a veterinarian is recommended.”**

The AVMA supports the factual statement “Duration of immunity for this product has not been evaluated.” Immunity was not demonstrated at any interval because the product’s efficacy was not fully proven; therefore it is appropriate that the labels of conditionally licensed products indicate that duration of immunity has not been evaluated.

We also support the concept of consulting with a veterinarian, but urge that the sentence “Consultation with a veterinarian is recommended.” should be decoupled from the duration of immunity phrasing to become a stand-alone sentence placed in a more general area of the label. Veterinarians offer guidance on a wide range of vaccine use issues, including indication for use, interval for revaccination, potential for adverse reactions and more. Therefore, the phrase should not be limited in interpretation to duration of immunity.

In the absence of label data, veterinarians may use professional judgment and clinical experience, and when available, peer-reviewed studies and veterinary organizational guidelines, to customize recommendations for patients receiving conditionally licensed products.

**4. Labels for conditionally licensed products should be black and white; no other color label is permitted.**

The AVMA supports the use of black and white labels.

**5. No Trade Names are permitted for any conditional license.**

The AVMA supports the continued absence of trade names for conditionally licensed biologics.

The AVMA is appreciative of CVB’s leadership in this area and is thankful for the opportunity to comment.

Respectfully,



Janet D. Donlin, DVM  
Assistant Executive Vice President  
JDD/ECG