

AVMA



American Veterinary Medical Association

January 5, 2007

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**Center for Veterinary Biologics Notice No. DRAFT-021  
Label Warning Statement for Serum and Plasma Products of Equine Origin**

Dear Sir or Madam:

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 75,000 members represent approximately 85% 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.

The AVMA appreciates that the Center for Veterinary Biologics (CVB) seeks to include cautionary warnings on labels of products to inform veterinary practitioners of possible adverse events. As we understand, CVB is proposing to require that biological products of equine serum or plasma origin intended for use in horses bear the following warning: "The use of equine serum and plasma products has been associated with hepatic disease in horses. The administration of this product, particularly if routine or repeated, may increase this risk."

The AVMA recognizes that equine serum and plasma biologics products are used for numerous reasons and that there may be adverse events from any product containing potentially antigenic, allogenic proteins. The AVMA's Council on Biologic and Therapeutic Agents (COBTA) and Clinical Practitioner's Advisory Committee (CPAC) has evaluated the situation concerning adverse events resulting from use of biological products of equine serum or plasma origin. It is the opinion of COBTA and CPAC that there is insufficient data to support this labeling language. Such action should be only taken when there is clear and substantiated association between medical conditions and the product. Substantiation of product causality as well as data involving associated adverse event reporting rates have not been made available to the veterinary profession. Until such time, the AVMA recommends that CVB does not finalize this draft notice until adequate information is made available to help support review and concurrence by the veterinary profession. To do otherwise, sets a potentially dangerous precedence for all other products. We welcome further dialogue between CVB and COBTA on this issue.

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The recognized need for such label precautions illustrates a critical need for fully developed, scientifically based, and statistically valid evaluations of biologics products to provide practitioners with a basis for developing health programs that maximize benefits and minimize associated risks for the patients under their care. An effective adverse event reporting system is one of the key elements of this process, and minimizes associated risks for the patients under their care.

Current adverse event reporting systems should be designed and implemented to effectively capture, analyze, and report adverse events. Practitioner commitment to adverse event reporting, and timely access for practitioners to current analysis of adverse event data, are essential to providing optimal patient care.

While the AVMA is committed to the continued availability of products that are pure, safe, potent and efficacious for animals, the AVMA also encourages continued development and strengthening of adverse event reporting systems. The AVMA is strongly in favor of a central reporting system that is transparent and appropriately informs the public regarding adverse reactions and/or the failure of biologics to protect animals. We recommend these reports follow a standardized, systematic template and that any compilation or interpretation of these reports be provided in a form that is useful to both biological firms and veterinarians. Presently, we believe there is a significant and urgent need for a strong vaccinovigilance reporting function within the USDA-APHIS Center for Veterinary Biologics. If such a system were available it would allow veterinary practitioners to effectively evaluate product information and optimize therapeutic judgment on a case-by-case basis.

We hope these comments provide CVB the input sought while providing the AVMA an opportunity to encourage CVB's implementation of a practical and informative adverse reporting system that helps to make important product information available to veterinary practitioners. Should you need further explanation of any comments offered please feel free to contact Dr. David Scarfe (847-285-6634; dscarfe@avma.org).

Sincerely,



Janet D. Donlin, DVM  
Assistant Executive Vice President

JDD/ADS