USDA

United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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Comments Due February 5, 2007

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. DRAFT-021

Subject: Label Warning Statement for Serum and Plasma Products of Equine Origin

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

I. PURPOSE

The purpose of this Notice is to inform interested parties that the Center for Veterinary Biologics (CVB) requires a warning on labeling for biological products of equine serum or plasma origin intended for use in horses.

II. BACKGROUND

The use of equine serum and plasma products has long been associated with hepatic disease in horses. While the occurrence of disease (Theiler's Disease or serum hepatitis, idiopathic acute hepatic disease, or acute hepatic failure) is uncommon, it is usually fatal. Tetanus antitoxin is often used as a routine prophylactic measure in the horse industry, particularly in periparturient mares and foals. Other serum and plasma products are also used prophylactically and for treatment.

III. ACTION

All labels filed subsequent to January 1, 2007, for antibody products containing, or derived from, equine serum or plasma should contain the following warning statement:

"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."

Submit revised labeling for currently licensed products no later than June 30, 2007. Existing inventory of previously approved labels that do not contain a risk statement may be used until January 1, 2008. Previously approved labeling that contains an alternatively worded risk statement will be considered on a case-by-case basis for acceptability for continued use.

This warning statement also should appear in Section VI.E of the Outline of Production. Update Outlines of Production on, or before, the next annual review.