Comments due August 6, 2007

CENTER FOR VETERINARY BIOLOGICS NOTICE DRAFT NO. 313

Subject: Labeling of Equine Influenza and Swine Influenza Vaccines

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

I. PURPOSE

The purpose of this notice is to notify veterinary biologics licensees, permittees, and applicants of a change in labeling of veterinary biologics containing swine influenza virus or equine influenza virus, as per Title 9 Code of Federal Regulations, Part 112.2(b). This notice does not pertain to autogenous products containing equine and/or swine influenza virus.

II. BACKGROUND

APHIS currently does not require the strains of the component influenza subtype(s) to be included on the labeling of equine influenza or swine influenza vaccines. Recently, however, antigenic shift and drift have been increasingly evident in viruses isolated from field cases of influenza. Information regarding the subtypes and strains included in licensed products, or the parent strain of recombinant/resortant/subunit products will aid in developing effective vaccination strategies for currently circulating influenza viruses in swine and horses.

III. GUIDANCE

The True Names of equine influenza-containing products currently do not include subtype designations and the Center for Veterinary Biologics (CVB) is not considering changing the True Names of equine influenza-containing products. The subtypes and strains included in equine and swine influenza-containing products should be disclosed on the label, however, as part of the indications statement. For recombinant/reassortant/subunit products, the subtype and strain of the parent strain should be provided. The strains should be designated according to accepted standards of influenza virus nomenclature (e.g. “A/equine/Miami/63(H3N8),” or “A/swine/Wisconsin/458/98(H1N1)”). Further identification of strains with commonly used, scientifically justified terms such as “A2,” “European,” “American,” “atypical,” or “classical,” should also be provided. If the product does not contain the N subtype gene, this information must also be disclosed on the labeling. In addition, the label should indicate, as part of the product claim, the subtype(s) and strain(s) of the influenza challenge virus(es) used to demonstrate efficacy of the product.

IV. ACTION

For swine and equine influenza products, the indications statement of all labels and Section VI of the Outline of Production should be revised to include the subtypes and strains of influenza contained in the product, and to indicate the subtype(s) and strain(s) of influenza used for challenge in the efficacy trial(s). Modifications to the Outline of Production and labels should be completed within one year from the date of this notice.