USDA
United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 14-06

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

FROM: Steven A. Karli */s/ Steven A. Karli*
Acting Director

SUBJECT: Safety Data to Support Using Multiple Strains of Potentially Immunosuppressive Viruses in the Same Modified Live Product

I. PURPOSE

The purpose of this Notice is to inform manufacturers that for certain agents, if combined with other agents in a modified live combination product, typical backpassage and field safety studies may not be sufficient.

II. BACKGROUND

The 1913 Virus Serum Toxin Act as amended by the 1985 Food Security Act, authorizes the USDA to ensure all veterinary biologics for sale and distribution in the United States are not worthless, contaminated, dangerous or harmful. The impact of multiple strains of potentially immunosuppressive agents on the immune system, particularly of neonates, is not well understood. Supplemental safety data may be required for certain proposed modified live products, to ensure safety.

III. POLICY

To assess the immunosuppressive effects of combining multiple potentially immunosuppressive agents in the same modified live product, additional safety data may be required, to ensure that new products are safe as previously licensed products. Agents may be considered immunosuppressive based on data published in scientific literature. Although data generated from backpassage and field safety studies are minimum requirements for modified live products, additional safety data may be required. An example of a new product that may require additional studies would be a modified live Bovine Virus Diarrhea vaccine that includes additional strains in a combination that has not been previously approved for the proposed route of administration. Reviewers will provide recommendations for specific products when developing product licensing plans.

IV. IMPLEMENTATION/ APPLICABILITY

This change is effective as of the date of this Notice. This policy applies to new products only.