

April 16, 2001

CENTER FOR VETERINARY BIOLOGICS NOTICE 01-04

Subject: Identification of Component Products in Combination Package Biologics

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

I. PURPOSE

The purpose of this notice is to clarify how firms should complete Part VI.C. of the Outline of Production for combination package products in accordance with 9 CFR 114.9(d). The US Veterinary Biological Product License for combination packages authorizes the use of a licensed liquid biological product, instead of an inert liquid, as the diluent for a desiccated licensed product. Outlines of Production for combination packages must clearly identify all finished products in the combination package. Historically, this information has been noted in variable formats and locations throughout the outline.

II. ACTION

Licensees and Permittees should update their Outlines of Production for combination package products to indicate all of the finished products that are packaged together under the combination Product Code. Section VI.C. should include the following appropriately completed statement, entering all of component Product Codes in the blank:

"The expiration date of the combination package is the earliest expiration date of the individual product components in accordance with 9 CFR 114.13. This combination package is composed of released product of Codes _____."

All Licensees and Permittees should bring their Outlines of Production into compliance with this notice at or before the next annual review.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics