April 2, 1999

CENTER FOR VETERINARY BIOLOGICS NOTICE 99-12

Subject: Determination of Expiration Dates for Biological Products

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

I. PURPOSE

The purpose of this Notice is to clarify how the Center for Veterinary Biologics (CVB) interprets 9 CFR 114.13 concerning the determination of expiration dates for veterinary biological products, and to indicate what specific information about the expiration date Licensees and Permittees should include in Outlines of Production.

II. INTERPRETATION

According to 9 CFR 114.13, the expiration date for each product should be computed from the date of the initiation of the potency test. The CVB interprets the initiation of the potency test to be the on-test date of the first potency test conducted on a serial of the product. The on-test date is considered to be the date that the product is introduced into the test system (i.e., the first day the product is injected into the animal or the first day the product is added to the microtiter plate, etc.).

III. OUTLINE OF PRODUCTION CHANGES

Licensees and Permittees should update their Outlines of Production for all products to indicate how the expiration date for each product is determined. The appropriately completed statement:

"The expiration date is __ months after the date of initiation of the first potency test." should be added to:

A. Part VI.C. of the Outline of Production for Vaccines, Bacterins, Antigens, Toxoids, and Diagnostic Test Kits,

B. Part VI.D. of the Outline of Production for Antiserum, Antitoxin, and Normal Serum, and

C. Part IV.C. of the Outline of Production for Allergenic Extracts.

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