United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

510 S. 17th Street,
Suite 104
Ames, IA 50010
(515) 232-5785
FAX (515) 232-7120

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 05-17

Subject: Dating Extension and Dilution Adjustment for Standard Reference Bacterin IRP ERB-5

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) is extending the dating of *Erysipelothrix rhusiopathiae* Standard Reference Bacterin IRP ERB-5 and adjusting the use dilution of *Erysipelothrix rhusiopathiae* Standard Reference Bacterin IRP ERB-5. Manufacturers of products containing Erysipelothrix Rhusiopathiae Bacterin are herein informed of changes in procedures for conducting potency tests according to 9 CFR 113.119.

II. BACKGROUND

The CVB is committed to providing quality references and reagents to their customers and stakeholders. The *Erysipelothrix rhusiopathiae* Standard Reference Bacterin IRP ERB-5 is scheduled to expire on September 15, 2005. Live animal testing at CVB indicates that this Standard Reference has undergone a gradual decline in potency. To ensure consistency for licensees using this Standard to potency test products containing *Erysipelothrix rhusiopathiae* antigens, the CVB has initiated the process of establishing and validating a new Standard Reference Bacterin. Until the new reference is established, validated, and made available to stakeholders, the CVB recognizes a need to extend the dating of the current *Erysipelothrix rhusiopathiae* Standard Reference Bacterin IRP ERB-5 and to make necessary adjustments to the dilution currently used in the mouse challenge potency assay described in 9 CFR 113.119.

III. ACTION

The expiration date for *Erysipelothrix rhusiopathiae* Standard Reference Bacterin IRP ERB-5 will be extended until September 15, 2006, or until a new reference is qualified. During this period, firms using Standard Reference Bacterin IRP ERB-5 to conduct the 9 CFR113.119 mouse potency assay should change the initial dilution from 1:2, as was

specified in CVB Notice No. 00-07, to undiluted. Firms should begin using the new dilution in any potency tests initiated over 30 days after the publication date of this Notice. A phase-in period for any new reference preparation will be announced at a later date as the new reference becomes available.

/s/ Richard E. Hill, Jr.

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