

March 3, 2008

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 08-04

Subject: Reinstatement and Dating Extension for Erysipelothrix Rhusiopathiae Standard Reference Bacterin, Serial 5

To: VS Management Team
Directors, Center for Veterinary Biologics
Biologics Licensees, Permittees, and Applicants
Area Veterinarians in Charge, VS
State Veterinarians

I. PURPOSE

The purpose of this Notice is to inform interested parties that the Center for Veterinary Biologics (CVB) is reinstating Erysipelothrix Rhusopathiae Standard Reference Bacterin, Serial 5 for use in testing in accordance with Title 9 Code of Federal Regulations, Part 113.119 with an expiration date of June 30, 2008.

II. BACKGROUND

The CVB is committed to providing quality references and reagents to their customers and stakeholders. Erysipelothrix Rhusopathiae Standard Reference Bacterin (ERB), Serial 5 was used as the reference for conducting testing in accordance with 9 CFR 113.119 until the fall of 2007.

On September 11, 2007, CVB Notice 07-14 was published. This Notice announced the availability of a new standard reference bacterin designated IRP 529(05) and indicated that firms should use this bacterin in testing conducted after November 10, 2007. IRP 529(05) is currently being withdrawn while additional testing is conducted at the CVB.

The CVB will be conducting additional animal testing to alleviate concerns expressed to us. Therefore, the previous reference, ERB Serial 5, will be reinstated with an expiration date of June 30, 2008, while the additional testing is conducted on IRP 529(05).

III. ACTION

Erysipelothrix Rhusiopathiae Standard Reference Bacterin, Serial 5 is reinstated with the publication of this Notice as the current reference bacterin for conducting testing in accordance with 9 CFR 113.119 with an expiration date of June 30, 2008. This Reference Bacterin preparation is to be used undiluted. When the additional testing on IRP 529(05) is complete, further guidance will be provided. For the interim, please ensure that the reference used in testing is reported on the APHIS Form 2008.

/s/ Richard E, Hill, Jr.

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