



October 2, 2006

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 06-20

Animal and Plant
Health Inspection
Service

Subject: Dating Extension and Dilution Adjustment for Selected Standard References

Veterinary Services

Center for Veterinary
Biologics

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

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I. PURPOSE

The purpose of this Notice is to inform interested parties that the Center for Veterinary Biologics (CVB) is extending the dating and/or adjusting the dilution of the Standard Reference Bacterins and Standard Reference Toxin listed below in Section III. Manufacturers of products containing the applicable antigen(s) are herein informed of changes in procedures for conducting potency tests according to the applicable Section of the 9 CFR Part 113 as noted below in Section III.

II. BACKGROUND

The CVB is committed to providing quality references and reagents to its customers and stakeholders. The Standard References listed below in Section III are nearing expiration, and assay data indicate that some of these references have undergone a gradual decline in potency. The CVB has initiated the process of establishing and validating new Standard References. To facilitate continued serial release until the new Standard References are made available to stakeholders, the CVB is extending the dating of the current Standard References listed in Section III and/or making necessary adjustments to the working dilution(s) currently used in the codified assays. A phase-in period for any new reference preparation will be announced as the new reference becomes available.

III. ACTION

Clostridium novyi type B toxin Standard Reference Toxin IRP 425:

The expiration date for Clostridium novyi type B Standard Reference Toxin IRP-425 will remain unchanged (i.e., no expiration date assigned). However, the Lo and L+ dilutions of Standard Reference Toxin IRP 425 for the mouse potency assay described in 9CFR 113.108 are being adjusted. A volume of 0.6 mL of IRP 425 diluted 1:62, plus 0.4 mL of diluent, is now equivalent to 0.1 Lo dose. A volume of 0.9 mL of IRP 425 diluted 1:62, plus 0.1 mL of diluent, is now equivalent to 0.1 L+ dose. These new working dilutions will become effective for all potency tests initiated more than 30 days after the publication date of this Notice.

Erysipelothrix rhusiopathiae Standard Reference Bacterin IRP ERB-5:

The expiration date for Erysipelothrix rhusiopathiae Standard Reference Bacterin IRP ERB-5 is extended to September 15, 2007, unless a new reference is available before that date. Continue to use this reference undiluted in the mouse assay described in 9CFR 113.119, as specified in CVB Notice 05-17.

Salmonella cholerasuis Standard Reference Bacterin IRP SCB-4:

The expiration date for Salmonella cholerasuis Standard Reference Bacterin IRP SCB-4 is extended until June 30, 2007, unless a new reference is available before that date. The initial working dilution (pre-dilution) for this reference in the mouse potency assay described in 9CFR 113.122 is being changed from 1:5 to undiluted. This new working dilution will become effective for all potency tests initiated more than 30 days after the publication date of this Notice.

Salmonella dublin Standard Reference Bacterin IRP SDB-3:

The expiration date for Salmonella dublin Standard Reference Bacterin IRP SDB-3 will be extended until September 15, 2008, unless a new reference is available before that date. The initial working dilution (pre-dilution) for this reference in the mouse potency assay described in 9CFR 113.123 is being changed from 1:10 to undiluted. This new working dilution will become effective for all potency tests initiated more than 30 days after the publication date of this Notice.

Salmonella typhimurium Standard Reference Bacterin IRP 460:

The expiration date for Salmonella typhimurium Standard Reference Bacterin IRP 460 is extended until June 30, 2008, unless a new reference is available before that date. The initial working dilution (pre-dilution) for this reference in the mouse potency assay described in 9CFR 113.120 is being changed from 1:10 to undiluted. This new working dilution will become effective for all potency tests initiated more than 30 days after the publication date of this Notice.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director