



February 17, 2011

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 11-04

**United States
Department of
Agriculture**

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Management Team

FROM: Richard E. Hill, Jr. /s/ *Richard E. Hill, Jr.*
Director
Center for Veterinary Biologics

SUBJECT: Expiration Date Extension and Discontinued Reagents: Salmonella
Standard Reference Bacterins

I. PURPOSE

The purpose of this document is to notify veterinary biologics manufacturers that the expiration dates of three standard Salmonella Reference Bacterins (Salmonella Choleraesuis Standard Reference Bacterin, Salmonella Dublin Standard Reference Bacterin, and Salmonella Typhimurium Standard Reference Bacterin) have been extended to June 30, 2011. This is to accommodate the industry's need for these reagents.

II. BACKGROUND

The CVB had initially supplied the standard references for use in the mouse tests codified in Title 9, Code of Federal Regulations (9 CFR), Parts 113.120, 113.122, and 113.123. The cited 9 CFR parts require a reference "supplied by or acceptable to APHIS." The supply of the current lots of the standard reference bacterins has become limited and a Notice to the industry, CVB Notice 09-23, was published on October 29, 2009, to inform industry that the reagents could no longer be supplied.

III. POLICY

Since there is still an industry need for these reagents and limited amounts are still available, we have extended the dating of the reference bacterins until June 30, 2011. By this time, firms will be expected to have their own reference bacterins made, tested, and qualified in host animals for serial release. If the codified mouse potency test will continue to be the serial release test, the reference should be validated for the codified test. If an *in vitro* test will become the serial release potency test, a reference should be validated according to the guidelines in Veterinary Services Memorandum 800.112, unless alternate arrangements have been made. In both cases, expiration dates will be assigned to the references, and firms will be expected to support reference dating accordingly.



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