



October 29, 2009

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 09-23

**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 December 31, 2010. After that date, the CVB will no longer distribute them.

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) Part 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 will become depleted by the end of 2010.

III. POLICY

By December 31, 2010, 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, efficacy should be correlated with the codified test. If an *in vitro* test will become the serial release potency test, efficacy should be correlated to that test and validated according to the guidelines in Veterinary Services Memorandum 800.112. 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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