



July 31, 2008

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 08-15

**United States
Department of
Agriculture**

Animal and Plant
Health Inspection
Service

Veterinary Services
Center for Veterinary
Biologics

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SUBJECT: Dating Extension for *Salmonella typhimurium* and *Salmonella dublin*
Standard Reference Bacterins

TO: VS Management Team (VSMT)
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 extending the dating of *Salmonella typhimurium* Standard Reference Bacterin, Lot No. IRP 460, and *Salmonella dublin* Standard Reference Bacterin, Lot No. IRP SDB Serial #3 (IRP SDB-3). Manufacturers of products containing these antigens are herein informed of an extension of dating of these potency references.

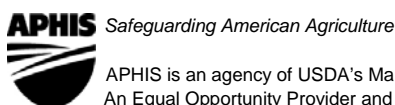
II. BACKGROUND

Salmonella typhimurium Standard Reference Bacterin IRP 460 expired on June 30, 2008; *Salmonella dublin* Standard Reference Bacterin IRP SDB-3 expires on September 15, 2008. To ensure consistency for those using these references in potency testing, the CVB will ultimately establish new Standard Reference Bacterins. Until these are made available, the CVB recognizes the need to extend the dating of the current Standard References, as specified below in Section III.

III. ACTION

***Salmonella typhimurium* Standard Reference Bacterin IRP 460**

The expiration date for *Salmonella typhimurium* Standard Reference Bacterin IRP 460 is extended until June 30, 2009, or until a new reference is available, whichever is earlier. Firms using this reference to conduct the 9 CFR 113.120 mouse potency assay must use undiluted reference bacterin as the initial test dilution. A phase-in period for any new reference will be announced when it becomes available.



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***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 30, 2009, or until a new reference is qualified, whichever is earlier. Firms using this reference to conduct the 9 CFR113.123 mouse potency assay must use undiluted reference bacterin as the initial test dilution. A phase-in period for any new reference will be announced when it becomes available.

Please follow the procedures outlined in Veterinary Services Memorandum No. 800.97 for requesting either of these references. Reagent Data Sheets, included with shipments of these references, provide instructions for use and storage.

/s/ Richard E. Hill, Jr.

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