



February 12, 2013

United States  
Department of  
Agriculture

**CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 13-04**

Animal and Plant  
Health Inspection  
Service

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

Veterinary Services

Center for Veterinary  
Biologics

**FROM:** Richard E. Hill, Jr. /s/ *Richard E. Hill, Jr.*  
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**SUBJECT:** Discontinued Bacterial Challenge Cultures

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**I. PURPOSE**

The purpose of this document is to notify veterinary biologics manufacturers that the Center for Veterinary Biologics (CVB) distribution of the following Bacterial Challenge Cultures will be discontinued:

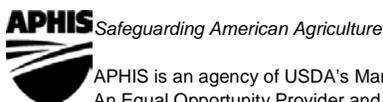
- *Bordetella bronchiseptica* challenge culture, Current Lot designation IRP 312
- *Salmonella choleraesuis* challenge culture, Current Lot designation IRP SCC serial #5 (9 CFR 113.122 / SAM 632)
- *Salmonella dublin* challenge culture, Current Lot designation IRP SDC serial #5 (9 CFR 113.123 / SAM 633)

**II. BACKGROUND**

The CVB laboratory routinely provides bacterial Standard Reference Preparations and Test Reagents, including challenge cultures, to veterinary biologics manufacturers in accordance with Veterinary Services Memorandum 800.97. Due to limited requests, the above three challenge cultures will no longer be produced for distribution by the CVB.

The *B. bronchiseptica* challenge culture is used in mouse potency tests patterned after several codified bacterial potency tests, including those discussed below.

The *Salmonella choleraesuis* and *S. dublin* challenge cultures indicated above are used in the codified mouse potency tests described in Title 9, Code of Federal Regulations, Parts 113.122 and 113.123 respectively. Both challenge cultures are designed with the codified 0.25 mL dose. However, the codified mouse LD<sub>50</sub> values are different (10-1,000 mouse LD<sub>50</sub> for *S. choleraesuis* and 1,000-100,000 mouse LD<sub>50</sub> for *S. dublin*).



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Additional testing details are provided in Supplemental Assay Method (SAM) 632 and SAM 633. The reagent data sheets for current lots provide basic preparation and use information. Copies of these documents are available on our website or upon request.

### **III. ACTION**

Over the course of the year, firms may continue to utilize our current reagent lots. However, efforts need to be made to prepare challenge culture lots in anticipation of the cessation of our distribution. The replacement lots may be propagated from the current CVB lot using our preparation information.

Alternatively, if firms would prefer to establish their own strain for challenge in the potency tests, these cultures/strains should be validated, tested, and approved by the CVB. Testing should include purity, identity, and equivalence to the currently used challenge. This information should be supplied to the firm's reviewer for CVB acceptance prior to use. Upon lot acceptance, the lot number (and if applicable strain information) should be incorporated into the applicable Outlines of Production or Special Outlines of Production.

### **IV. IMPLEMENTATION/ APPLICABILITY**

A year from the publication date of this Notice, the CVB will no longer supply these challenge cultures.