



January 22, 2009

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 09-02

**United States
Department of
Agriculture**

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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TO: VS Management Team
Directors, Center for Veterinary Biologics
Biologics Licensees, Permittees, and Applicants
Area Veterinarians in Charge, VS
State Veterinarians

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

SUBJECT: Dilution of Preservative Screening for Broth-Based Sterility Tests

I. PURPOSE

The purpose of this Notice is to inform interested parties that the Center for Veterinary Biologics (CVB) is conducting a screening test regarding dilution of preservative in accordance with Title 9, Code of Federal Regulations (9 CFR) 113.25(d) for broth-based sterility tests. One additional container, with the volume of media indicated in the Outline of Production, is inoculated with the serial being confirmatory or check tested and approximately 100 colony-forming units of the appropriate indicator organism. If growth does not occur in this tube, the CVB will test the dilution of preservative information for the product code utilizing the serial in question.

II. BACKGROUND

Manufacturers are required under 9 CFR 113.25(d) to determine the ratio of inoculum to medium which shall result in sufficient dilution of such product to prevent bacteriostatic and fungistatic activity. The CVB has been screening the media amounts as serials are picked for check or confirmatory testing by inoculating an extra container with indicator organism and the serial. For Activity Year 2007 (September 1, 2006 to August 31, 2007) and part of Activity Year 2008 (September 1, 2007 to January 10, 2008), the following results were obtained:

Activity Year	Killed products CFR 113.26		Live products 9 CFR 113.27(a)	
	No. tested	No. "No growth"	No. tested	No. "No growth"
2007	177	15	135	10
2008	50	2	41	1
Total	227	17	176	11



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The above data suggest that for 7% of the serials tested at CVB, the dilution of preservative study may not have provided an adequate dilution to result in a valid test.

III. ACTION

The CVB will begin repeating dilution of preservative studies (utilizing the volume of media indicated in the Outline of Production) per 9 CFR 113.25(d) and the current version of SAM 903 when the above screening test suggests that the media volume being used is insufficient. This action will be initiated 30 days after the publication of this Notice. This will add approximately 3 weeks to serial testing for those serials slated for further testing. If CVB's dilution of preservative test indicates interference at the volume cited in the Outline of Production, CVB testing will be reported as a NT (no test) result for the sterility testing and an unsatisfactory result for the dilution of preservative test. The APHIS Form 2008 will be processed as NRL (not to be released) - the serial will not be marketed.

In the case of confirmatory testing conducted during the licensure process, no license will be issued until the dilution of preservative testing is reevaluated and the issue of media volume is resolved. In the case of check testing for a licensed product, the serial will be reported out as unsatisfactory. Further regulatory action will be taken as appropriate until the issue of media volume is resolved.