



May 11, 2010

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 10-03

**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: Extension of Dating for Clostridium Novyi type B antitoxin, IRP 507(04)

I. PURPOSE

This notice informs interested parties that the Center for Veterinary Biologics is extending the dating of Clostridium Novyi type B antitoxin, IRP 507(04).

II. BACKGROUND

This reagent is used in potency testing products containing a Clostridium Novyi Bacterin Toxoid fraction. The test is codified in Title 9, Code of Federal Regulations Part 113.108 and detailed in Supplemental Assay Method 207. It uses immune rabbit serum in a toxin-anti toxin neutralization test with mice as an indicator. This reagent is the standard antitoxin for the test. The dilution and the neutralization pattern have been maintained from 2005 to present supporting the continued stability of the reagent.

III. ACTION

The expiration date for Clostridium Novyi type B antitoxin, IRP 507(04) is extended until May 31, 2013.



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