



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 15-03

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

FROM: Byron E. Rippke
Director

**BYRON
RIPPKE**

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of Agriculture, cn=BYRON RIPPKE,
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Date: 2015.03.27 14:43:13 -05'00'

SUBJECT: Adjustment for *Clostridium perfringens* Type C and Type D Reagents

I. PURPOSE

The purpose of this document is to notify veterinary biologics manufacturers that the use dilutions of two Clostridial antitoxins (*Clostridium perfringens* Type C and *Clostridium perfringens* Type D) and the L₊ of *Clostridium perfringens* Type D toxin have been adjusted for the test procedures codified in title 9, *Code of Federal Regulations* (9 CFR), section 113.112(c) and section 113.111(c).

II. BACKGROUND

The Center for Veterinary Biologics (CVB) conducts yearly validation testing on Clostridial reagents in comparison to the WHO International Standard antitoxins. Upon testing, it was determined that adjustments needed to be made to the *C. perfringens* Type C and Type D reagents.

After confirmatory testing was conducted, the following adjustments have been made:

C. perfringens Type C antitoxin, IRP 585-A: will be used at a 1:50 use dilution.

C. perfringens Type D antitoxin, IRP 249: will be used at a 1:44 use dilution.

C. perfringens Type D toxin, IRP 450: the L₊ has been changed to 0.9 mL, the L_o remains the same at 0.6 mL.

III. POLICY

These reagents can still be obtained from the CVB. The reagent data sheets will be updated to reflect the changes. We will continue to monitor these reagents yearly.

IV. IMPLEMENTATION/ APPLICABILITY

This change is effective upon publication of this notice.