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

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.