CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 20-05

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

FROM: Byron E. Rippke
Director

SUBJECT: Name Change for Biologicals containing Glaesserella parasuis, formerly Haemophilus parasuis, and Clostridioides difficile, formerly Clostridium difficile

I. PURPOSE:

The intended purpose of this Notice is to inform licensees, permittees, and applicants of a change in the True Name of products containing Haemophilus parasuis and Clostridium difficile.

II. BACKGROUND

Haemophilus parasuis has been renamed Glaesserella parasuis and Clostridium difficile has been renamed Clostridioides difficile as a result of taxonomic investigations. The scientific community has endorsed this new name and it is included in the List of Prokaryotic Names with Standing in Nomenclature site: [http://www.bacterio.net/index.html](http://www.bacterio.net/index.html). Since CVB uses standard nomenclature when reasonably possible, CVB-assigned True Names for products containing these organisms will now include Glaesserella parasuis and Clostridioides difficile.

III. ACTION

CVB will use the new nomenclature for products in the prelicense stage. For licensed and permitted products, Outlines of Production and labeling should be revised. Firms may continue to use Haemophilus parasuis on international labels only. All affected firms must comply within 2 years of the date of this notice.

CVB will reissue a new license or permit within 60 days of the date of the notice. It is not necessary for the firm to make a submission to request reissuance of a new license with an updated True Name.

IV. IMPLEMENTATION

This action is effective immediately.