CENTER FOR VETERINARY BIOLOGICS NOTICE 19-07

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

FROM: Byron E. Rippke
Director

SUBJECT: Discontinued Availability of Pasteurella multocida 169 (Porcine) Bacterin

I. PURPOSE

The purpose of the document is to notify veterinary biologics manufacturers that the Center for Veterinary Biologics (CVB) will stop distributing Pasteurella multocida 169 (Porcine) Bacterin after December 31, 2020.

II. BACKGROUND

The CVB laboratory has routinely provided reference Pasteurella multocida 169 (porcine) bacterin to veterinary biologics manufactures. Due to reduced resources, the CVB is discontinuing supply of this reagent.

III. ACTION

Firms must qualify a reference bacterin for use in swine after December 31, 2020, if testing a bacterin for potency by title 9, Code of Federal Regulations, section 113.121. The Outline of Production, Section V.C, must include information regarding the Pasteurella multocida reference bacterin used for serial release testing. This information must be supplied to the firm’s reviewer for CVB acceptance prior to use.

IV. IMPLEMENT/APPLICABILITY

CVB will stop shipping this reagent December 31, 2020. Complete any necessary Outline of Production changes by the same date.