United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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August 31, 2009

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 09-21

TO: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics
Area Veterinarians in Charge, VS
State Veterinarians

FROM: Richard E. Hill, Jr. /s/ Richard E. Hill, Jr.
Director
Center for Veterinary Biologics

SUBJECT: Transition Period for Implementation of a New Lot of Porcine Pasteurella Multocida Standard Reference Bacterin

I. PURPOSE

The purpose of this notice is to inform interested parties that a new lot of Porcine Pasteurella Multocida Standard Reference Bacterin is available for use.

II. BACKGROUND

The CVB has supplied Pasteurella Multocida Standard Reference Bacterin to be used in testing in accordance with 9 CFR 113.121. The current lot is Serial 3. It is currently being used without any starting dilution and has a PD_{50} of 8.6.

A new lot, IRP 573(08), has been prepared using a lot of inactivated culture prepared in accordance with a filed Outline of Production by a manufacturer. This formalin inactivated culture was adjuvanted with aluminum hydroxide, filled into final containers, labeled, and tested for potency in mice. It has a PD_{50} of 16.2.

III. POLICY

The expiration date of Serial 3 is extended for an additional six months to December 31, 2009, to create a transition period where manufacturers may use either Serial 3 or IRP 573 (08) undiluted to test serials of product. All test results should be indicated on the APHIS Form 2008 with notations as to which reference was used.

By December 31, 2009, manufacturers should have completed the transition process to use only IRP 573(08).

If manufacturers find that the new reference is too potent for their use, the possibility of employing a 1:2 dilution will be considered in December 2009, and comments should be forwarded to your reviewer concerning this issue. Alternatively, it will be possible to qualify a further dilution of the reference bacterin by a host animal efficacy study. The CVB recommends that firms contact their reviewers with a protocol for the study prior to its initiation.

The CVB anticipates conducting a swine efficacy study using the new lot of reference bacterin with further guidance provided at the conclusion of the test.