CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 10-07

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

    Director
    Center for Veterinary Biologics

SUBJECT: Extension of Dating for Pasteurella Multocida Type A Standard Reference Bacterin, IRP 573 (08); Pasteurella Multocida Standard Reference Bacterin, IRP PMA 1062 Serial 2; and Clostridium haemolyticum spore preparation IRP 526 (06)

I. PURPOSE

This Notice informs interested parties that the Center for Veterinary Biologics (CVB) is extending the dating of three reagents provided through the CVB in accordance with Veterinary Services Memorandum 800.97:

- Pasteurella Multocida Type A Standard Reference Bacterin, IRP 573 (08)
- Pasteurella Multocida Standard Reference Bacterin, IRP PMA 1062 Serial 2
- Clostridium haemolyticum spore preparation IRP 526 (06)

II. BACKGROUND

The CVB supplies the Standard Reference Bacterin for porcine Pasteurella Multocida Bacterins tested in accordance with Title 9, Code of Federal Regulations (9 CFR), Part 113.121. The current expiration date of this reference bacterin is June 6, 2010. Recent testing utilizing this reagent indicates that it is still potent. Therefore, the CVB will extend the dating for this bacterin for an additional 24 months.

The CVB supplies the Standard Reference Bacterin for bovine Pasteurella Multocida Bacterins tested in accordance with 9 CFR 113.121. Testing indicates that this bacterin continues to show potency. The CVB is currently extending this dating to allow for the preparation of a new lot of this reference bacterin.

The CVB supplies Clostridium haemolyticum spore preparation that is used as a challenge preparation for testing in accordance with 9 CFR 113.107. Testing to confirm continued potency is in progress. The CVB will extend this dating for 24 months.
III. ACTION

The expiration date for Pasteurella Multocida Type A Standard Reference Bacterin, IRP 573 (08) is extended until June 30, 2012.

The expiration date for Pasteurella Multocida Standard Reference Bacterin, IRP PMA 1062 Serial 2 is extended until June 30, 2012.

The expiration date for Clostridium haemolyticum spore preparation IRP 526 (06) is extended until January 31, 2012.