United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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February 13, 2006

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 06-03

Subject: Potential Contamination of Porcine Kidney Cells

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

I. PURPOSE

The purpose of this notice is to inform interested parties that it has come to the attention of the Center for Veterinary Biologics (CVB) that some porcine kidney cell lines are contaminated with extraneous porcine circovirus type 1. This notice provides actions for licensees, permittees, and applicants to address this issue.

II. BACKGROUND

The CVB, under authority of the Virus-Serum-Toxin Act and Title 9 Code of Federal Regulations (9 CFR), requires that all veterinary biological products be tested and shown to be free of contaminating agents to ensure purity. Current requirements for cell lines used in the production of biologics, as specified in 9 CFR 113.52, include tests for detection of extraneous viruses by the detection of cytopathogenic and/or hemadsorbing agents and by the fluorescent antibody technique.

III. ACTION

According to 9 CFR 113.47(b), under certain circumstances, additional testing for extraneous viruses may need to be conducted. Biologics licensees and permittees which manufacture or distribute products that utilize porcine kidney cell lines as a substrate should provide the CVB with data demonstrating that these cells are free of porcine circovirus type 1 contamination. Firms should provide their reviewers with this data within 6 months of the date of this notice. Upon review of the data, firms may be requested to submit Master Cell Stock samples to the CVB for extraneous agent testing by the fluorescent antibody technique described in 9 CFR 113.47. In the event that testing by the firm or the CVB demonstrates the presence of porcine circovirus type 1 or any other contaminant, the firm should immediately cease preparation, distribution, and sale of products prepared with contaminated cell stocks. As required by 9 CFR 116.5, if contaminants are discovered by the firm, the CVB must be immediately notified.

/s/ Byron E. Rippke for

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics