



July 21, 2009

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 09-15

**United States
Department of
Agriculture**

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Management Team
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FROM: Richard E. Hill, Jr. /s/ Richard E. Hill, Jr.
Director
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SUBJECT: Autogenous Vaccines Containing Porcine Circovirus

I. PURPOSE

This notice informs interested parties that the Center for Veterinary Biologics (CVB) is restricting the use of autogenous biologics containing porcine circovirus (PCV).

II. BACKGROUND

PCV is a non-enveloped, single-stranded, circular DNA virus classified in the virus family *Circoviridae*. PCV is widespread throughout the U.S. swine industry, is extremely stable in the environment, and is generally resistant to common disinfectants and killing agents (inactivation).

Title 9, Code of Federal Regulations (9 CFR), Part 113.113(c)(2), states that each serial or subserial of autogenous viral product other than the first serial or subserial produced from an isolate shall meet the applicable general requirements prescribed in 9 CFR 113.200 and the special requirements prescribed in this section.

III. POLICY

Before a licensed veterinary biologics establishment prepares an autogenous biologic containing PCV for use in herds other than the herd of origin, the killing agent (including inactivation kinetics) and tests to assure complete inactivation must be included in the approved Outline of Production, and must have been approved specifically for PCV. If the general requirements prescribed in 9 CFR 113.200(a) have not been approved specifically for PCV, the use of the autogenous biologic shall be limited to the herd of origin.



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