



December 20, 2010

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 10-10

**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
Area Veterinarians in Charge
State Veterinarians

FROM: Richard E. Hill, Jr. /s/Richard E. Hill, Jr.
Director
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SUBJECT: Follow-up Sterility Check Testing

I. PURPOSE

The purpose of this Notice is to inform interested parties that the Center for Veterinary Biologics (CVB) will begin follow-up sterility testing when *Mycoplasma* contamination check testing, in accordance with Title 9, Code of Federal Regulations (9 CFR), Part 113.28, shows bacterial or fungal growth that cannot be attributed to sources other than the serial being tested.

II. BACKGROUND

Manufacturers are required under 9 CFR 113.28 to test live viral products, master cell stock, and master seed viruses for *Mycoplasma* contamination. This test is currently conducted by passage of the material (serial or master seed) on media permissive for *Mycoplasma* growth. Controls for *Mycoplasma* media sterility, aseptic technique, etc., are conducted per the current version of Supplemental Assay Method (SAM) 910. When growth is detected on the *Mycoplasma* media that cannot be ascribed to sources other than the serial or lot of master seed, sterility of the material is of concern.

III. ACTION

When the CVB cannot rule out the serial or master seed as the source of bacterial or fungal contamination occurring during *Mycoplasma* check testing in accordance with 9 CFR 113.28, confirmatory sterility testing will be conducted. This may add approximately 3 weeks to testing. If the CVB's sterility test indicates contamination, the CVB testing will be reported as a no test for the *Mycoplasma* testing and unsatisfactory for sterility testing. The serial or lot of master seed's overall disposition will be reported as unsatisfactory.



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