CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 10-10

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

    Director
    Center for Veterinary Biologics

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.