



July 20, 2011

**CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 11-18**

**United States  
Department of  
Agriculture**

Animal and Plant  
Health Inspection  
Service

Veterinary Services

Center for Veterinary  
Biologics

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

**FROM:** Richard E. Hill, Jr. /s/ *Richard E. Hill, Jr.*  
Director  
Center for Veterinary Biologics

**SUBJECT:** Virus Inactivation and Safety Test for Rabies Virus Bulks,  
Title 9, Code of Federal Regulations (9 CFR), Part 113.209

**I. PURPOSE**

The purpose of this notice is to clarify testing expectations when animals injected with test bulk die between the 4<sup>th</sup> and 21<sup>st</sup> day post injection.

**II. BACKGROUND**

The 9 CFR, Part 113.209 (d)(2)(i), requires inactivated rabies bulk samples from each serial to be injected intracerebrally into 20 mice and into each cerebral hemisphere of 2 rabbits. The animals are observed daily for 21 days. If no unfavorable reactions occur the bulk is satisfactory.

If any of the animals die between day 4 and 21 of the observation period, the brain material is tested by either the fluorescent antibody (FA) or serum neutralization (SN) tests and inoculated into 5 more mice and observed for 14 days.

**III. POLICY**

Brain material from any dead animal and each brain of the subsequent 5 mice is assessed by the FA or SN test for the presence or absence of live rabies virus. If the presence of rabies virus is confirmed in any test, the serial is unsatisfactory for use.

**IV. IMPLEMENTATION/APPLICABILITY**

The policy presented is currently in effect.



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