



July 26, 2013

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 13-10

Animal and Plant
Health Inspection
Service

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

Veterinary Services

FROM: Richard E. Hill, Jr. /s/ *Richard E. Hill, Jr.*
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SUBJECT: Changes to the Rabies Virus NIH Potency Test Validity Requirements

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I. PURPOSE

This Notice informs licensees, permittees, and applicants of the Center for Veterinary Biologics (CVB) intent to eliminate the median lethal dose (LD₅₀) upper limit for the challenge virus as a validity requirement when conducting the Rabies Virus NIH potency test.

II. BACKGROUND

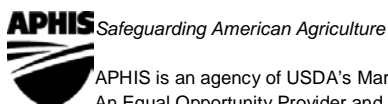
Supplemental Assay Method (SAM) 308 describes the current procedure for conducting the Rabies Virus NIH potency test according to the requirements specified in Title 9, Code of Federal Regulations, Part 113.209(d)(3). For a valid challenge, SAM 308 requires the LD₅₀ to be between 12 and 50 LD₅₀ before determining a serial's relative potency (RP) value. This has required repeating otherwise satisfactory tests if the challenge LD₅₀ was greater than the upper limit. Repeated testing has demonstrated the serials have acceptable potency in a valid NIH assay. CVB has found no indication an upper limit is necessary for test validity. In an effort to reduce the number of animals required for rabies testing, the CVB intends to eliminate the upper limit LD₅₀ for a valid challenge when conducting the Rabies Virus NIH potency test.

III. POLICY

The CVB has eliminated the upper limit LD₅₀ for a valid challenge as a validity requirement when conducting the Rabies Virus NIH potency test. For a valid challenge, the LD₅₀ is now ≥ 12 . SAM 308 will be amended to reflect this change.

IV. IMPLEMENTATION/ APPLICABILITY

This change will be effective immediately.



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