



November 6, 2006

United States  
Department of  
Agriculture

**CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 06-23**

Animal and Plant  
Health Inspection  
Service

Subject: Production Changes for Rabies Vaccines

Veterinary Services

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

Center for Veterinary  
Biologics

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**I. PURPOSE**

The purpose of this notice is to inform licensees, permittees, and applicants of the policy of the Center for Veterinary Biologics (CVB) regarding changes in production methods of Rabies Vaccines. Standard requirements for Rabies Vaccines are outlined in Title 9 Code of Federal Regulations (9 CFR) Part 113.209 and 113.312. Veterinary Services Memorandum 800.70 provides guidance regarding rabies vaccine immunogenicity protocols.

**II. BACKGROUND**

The CVB is committed to ensuring licensed veterinary biologics are pure, safe, potent, and efficacious. The efficacy of rabies vaccination of domestic animals is especially important as domestic animals represent a buffer between wildlife rabies reservoirs and humans. Rabies Vaccines for wildlife also aid in protecting the human population against this deadly disease. Therefore, CVB has assured State and Federal public health authorities that even the most minor manufacturing changes for Rabies Vaccines will be supported by full efficacy data.

**III. ACTION**

Any change or variation in the manufacture of a Rabies Vaccine must be supported by host animal efficacy data in each species for which the vaccine is recommended, in accordance with 9 CFR 113.209 and 113.312. This applies both to changes in Outlines of Production or Special Outlines, and requests for deviations in the manufacturing process that do not reflect currently approved Outlines of Production.

/s/ Richard E. Hill

Richard E. Hill, Jr.  
Director



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