



August 30, 2013

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 13-12

**United States
Department of
Agriculture**

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

1920 Dayton Avenue
PO Box 844
Ames, IA 50010

(515) 337-6100

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

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

SUBJECT: Issuance of a Conditional License for Rift Valley Fever Vaccine,
Modified Live Virus

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional license to Zoetis, Inc., Establishment No. 190, Lincoln, Nebraska, for the manufacture and distribution of Rift Valley Fever Vaccine, Modified Live Virus.

A veterinary biological product regulated under the Virus-Serum-Toxin Act must be shown to be pure, safe, potent, and efficacious before a veterinary biological product license may be issued. The regulations in Title 9, Code of Federal Regulations, Part 102, regarding the licensing of veterinary biological products provide that a conditional veterinary biological product license may be issued to meet an emergency condition, limited market, local situation, or special circumstance. The special circumstance addressed here is the need for the vaccine in the event of an emergency condition. Domestic distribution will be under APHIS control as part of an official animal disease control program.

Conditionally licensed products are required to be pure and safe, and have a reasonable expectation of efficacy. This conditional license was issued on the basis that the licensee has demonstrated the product has a reasonable expectation of efficacy. Safety of the product has been established through several safety studies. The conditional license will expire 2 years from the date of the license.



Safeguarding American Agriculture

APHIS is an agency of USDA's Marketing and Regulatory Programs
An Equal Opportunity Provider and Employer

Federal Relay Service
(Voice/TTY/ASCII/Spanish)
1-800-877-8339