



February 26, 2009

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 09-03

**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
Area Veterinarians in Charge, VS
State Veterinarians

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

SUBJECT: Issuance of a Conditional License for *Escherichia Coli* Bacterial Extract

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to EpiTopix, LLC, Establishment No. 365, Willmar, Minnesota, for the manufacture and distribution of *Escherichia Coli* Bacterial Extract.

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 (9 CFR) Part 102 regarding the licensing of biological products provide that a conditional veterinary biological product license may be issued to meet an emergency situation, limited market, local situation, or other special circumstances. The special circumstance addressed here is the absence of other licensed veterinary biological products for use in reducing the prevalence and shedding of *Escherichia coli* O157:H7 in cattle.

This conditional license was issued following the acceptance of data supporting product purity, product safety under normal conditions of use in field safety trials, and demonstration that the product has a reasonable expectation of efficacy. The conditional license will expire one year from the date of the license. In accordance with 9 CFR 102, progress acceptable to APHIS toward regular licensure must be made in order for APHIS to consider reissuance of the conditional license. EpiTopix, LLC, has provided to APHIS a plan and timeline for completion of the work required to support full licensure, and APHIS will monitor and evaluate the firm's progress during the year of conditional licensure.



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