



October 1, 2012

**CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 12-19**

**United States  
Department of  
Agriculture**

Animal and Plant  
Health Inspection  
Service

Veterinary Services

Center for Veterinary  
Biologics

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

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

**SUBJECT:** Issuance of a Conditional License for Polypropyl Immunostimulant

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Sass & Sass, Inc., Establishment No. 637, Oak Ridge, Tennessee, for the manufacture and distribution of Code 9380.00.

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 absence of other products used as therapeutics for symptoms associated with feline rhinotracheitis virus infection.

Conditionally licensed products are required to be pure and safe, and have a reasonable expectation of efficacy. This conditional license was issued following acceptance of data supporting the product has demonstrated a reasonable expectation of efficacy, is safe under normal conditions of use in field safety trials, and has acceptable purity. The conditional license will expire 2 years from the date of the license. APHIS will evaluate the firm's progress throughout the next 2 years toward regular licensure in order to consider reissuance of the conditional license.



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