



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 15-10

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

FROM: Byron E. Rippke **BYRON**
Director **RIPPKE**

SUBJECT: Issuance of a Conditional License for Canine Atopic Dermatitis
Immunotherapeutic

Digitally signed by BYRON RIPPKE
DN: c=US, o=U.S. Government,
ou=Department of Agriculture,
cn=BYRON RIPPKE,
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The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Zoetis Inc., Establishment No. 190, Lincoln, Nebraska, for the manufacture and distribution of Canine Atopic Dermatitis Immunotherapeutic.

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 a biological intervention for canine atopic dermatitis in order to afford veterinarians another treatment option to help mitigate the potential impact of long-term usage of chemotherapeutic agents.

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 a reasonable expectation of efficacy was demonstrated during field trials conducted in dogs that had been clinically diagnosed with canine atopic dermatitis. The conditional license will expire one year from the date of the license. APHIS will evaluate the firm's progress throughout the next year toward regular licensure in order to consider reissuance of the conditional license.