



CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 19-12

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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

FROM: Byron E. Rippke
Director

SUBJECT: Issuance of a Conditional License for Avian Reovirus Vaccine,
Killed Virus

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Biomune Company, Establishment No. 368, Lenexa, Kansas, for the manufacture and distribution of Avian Reovirus Vaccine, Killed Virus.

A veterinary biological product regulated under the Virus-Serum-Toxin Act must prove to be pure, safe, potent, and efficacious before issuing a veterinary biological product license. The regulations in title 9, *Code of Federal Regulations*, [part 102](#) regarding the licensing of biological products provide that APHIS may issue a conditional veterinary biological product license to meet an emergency situation, limited market, local situation, or special circumstance. The special circumstance addressed here is the need for a product to provide a vaccination against tenosynovitis caused by emerging variants of Reovirus in chickens.

Conditionally licensed products are required to be pure and safe, and have a reasonable expectation of efficacy. APHIS issued the conditional license on the basis that Biomune Company has demonstrated that the product has a reasonable expectation of efficacy. Field safety trials established the safety of the product. Biomune Company has provided a written commitment to APHIS to complete studies to demonstrate the efficacy of this product and to conduct any other work required for full licensure. APHIS will evaluate their progress later this year. The conditional license will expire one year from the date of the license.