



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 18-02

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

FROM: Byron E. Rippke
Director

SUBJECT: Issuance of a Conditional License for Avian Paramyxovirus Vaccine,
Type 1, Killed Virus

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Arko Laboratories Ltd., Establishment No. 337, Jewell, Iowa, for the manufacture and distribution of Avian Paramyxovirus Vaccine, Type 1, Killed 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 availability of a vaccine against avian paramyxovirus type I approved for use in pigeons.

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 that the product has a reasonable expectation of efficacy. Safety of the product has been established through a safety study. APHIS will evaluate their progress throughout the next year. The conditional license will expire 1 year from the date of the license.