

March 31, 2000

CENTER FOR VETERINARY BIOLOGICS NOTICE 00-05

Subject: Issuance of a Conditional License for Lawsonia Intracellularis Vaccine,
Avirulent Live Culture

To: Area Veterinarians in Charge, VS
State Veterinarians
Veterinary Services Management Team
Directors, Center for Veterinary Biologics

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Boehringer Ingelheim Vetmedica, Inc., Establishment No. 124, St. Joseph, Missouri, for the manufacture and distribution of Lawsonia Intracellularis Vaccine, Avirulent Live Culture.

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 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 special circumstance. The special circumstance addressed here is the need for a product to aid in the prevention of porcine proliferative enteropathy. Conditionally licensed products are required to be pure and safe, and have a reasonable expectation of efficacy.

The conditional license was issued on the basis that Boehringer Ingelheim Vetmedica, Inc. has demonstrated that the product has a reasonable expectation of efficacy. Safety of the product has been established through back passage studies and field safety trials. Boehringer Ingelheim 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 in one year.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics