

August 30, 2000

CENTER FOR VETERINARY BIOLOGICS NOTICE 00-13

Subject: Issuance of a Conditional License for
Avian Influenza Vaccine, Killed Virus, H5 Subtype

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 Maine Biological Laboratories, Establishment No. 240, Waterville, Maine, for an Avian Influenza Vaccine, Killed Virus, H5 Subtype.

A veterinary biological product regulated under the Virus-Serum Toxin Act must be shown to be pure, safe, 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 other special circumstance. The special circumstance addressed here is to have potential availability of an inactivated H5 Subtype Vaccine for use in chickens by poultry producers. There is no other licensed vaccine currently available for the prevention of disease, in chickens, due to Avian Influenza Virus, H5 Subtype.

The conditional license was issued following the acceptance of data supporting purity and having a reasonable expectation of efficacy and field safety. Domestic distribution and use of this product is restricted to use "under the supervision or control of USDA, APHIS, Veterinary Services, as part of an official USDA animal disease control program". The license will expire in 1 year. Progress toward regular licensure must be pursued for reissuance of the conditional license. The firm is required to perform additional studies to establish efficacy and product potency before APHIS will issue a regular product license.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Licensing and Policy Development