



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 14-07

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

FROM: Byron E. Rippke /s/ *Byron E. Rippke*
Acting Director

SUBJECT: Issuance of a Conditional License for Feline Interleukin-2
Immunomodulator, Live Canarypox Vector

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional license to Merial, Inc., Establishment No. 298, Athens, Georgia, for the manufacture and distribution of Feline Interleukin-2 Immunomodulator, Live Canarypox Vector.

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 the vaccine for the post-surgical treatment of feline fibrosarcoma. The product will be sold to licensed veterinarians; that is, the license bears the restriction, "For use by or under the supervision of a veterinarian."

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 the product has a reasonable expectation of efficacy. Safety of the product has been established through several safety studies. The conditional license will expire 2 years from the date of the license.