



December 20, 2006

**United States
Department of
Agriculture**

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 06-25

Subject: Issuance of a Conditional License for Lymphocyte T-Cell
Immunomodulator

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

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to T-Cyte Therapeutics, Inc., for the manufacture and distribution of Lymphocyte T-Cell Immunomodulator.

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 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 circumstances. The special circumstance addressed here is the absence of other licensed veterinary biological products for use as an aid in the treatment of diseases associated with feline leukemia virus or feline immunodeficiency virus infection in cats.

This conditional license was issued following the acceptance of data supporting product purity, product safety under normal conditions of use (field safety), and demonstration that the product has a reasonable expectation of efficacy. This license will expire in one year. In accordance with 9 CFR Part 102, progress toward regular licensure must be pursued for reissuance of the conditional license.

/s/ Byron E. Rippke for

Richard E. Hill, Jr.
Director



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