

February 10, 2005

To Whom It May Concern:

APHIS TEST KITS AND KIT COMPONENTS, SECTION 3-8-22 STATES:

“Test kits manufactured to diagnose human conditions (e.g., diseases, metabolic imbalances, pregnancy, etc.) or for general laboratory uses unrelated to the diagnosis of human conditions (e.g., DNA sequencing) **do not** require a VS permit, regardless of any animal-derived component in the kits. These test kits must be prepackaged, labeled, and ready for use.”

In accordance with the **APHIS Animal Product Manual** (08/2003-32 PPQ, VRS), as per section 3-8-22, Test Kits and Kit Components, the following statement applies to this shipment:

The product being shipped to **company** consists of a Diagnostic Kit and its respective components that are prepackaged, labeled accordingly, and ready for use.

The Kit is manufactured for the ***in-vitro* diagnosis of human conditions** and is not intended to diagnose infectious animal diseases. The Kit is directed against human **Thyroid Stimulating Hormone (TSH)**.

The product is manufactured and produced in Canada and **does not come from a facility where work with exotic viruses affecting livestock and avian species is conducted.**

The product is non-hazardous, non-infectious, does not contain any **genes, and does not express products of exotic livestock or poultry disease agents.**

Sincerely,

Christina Kirwan
Director of Corporate Affairs