



ANOGEN - A Division of YES Biotech Laboratories Ltd.

2355 Derry Road East, Unit 23, Mississauga, ON L5S 1V6

March 19, 2004

To Whom It May Concern:

In accordance with the **APHIS Animal Product Manual** (08/2003-32 PPQ, VRS), as per Table 3-8-7, Regulatory Action to Take on Live Laboratory Mammals and their Associated Materials, the following statements apply to this shipment:

The product being shipped to **company** consists of polyclonal antibodies purified **from rabbit blood fractions**. The product is directed against human **Hepatitis C Virus (HCV) antigen**.

The product is manufactured for **in vitro** research use only. This product is **not** for diagnostic or therapeutic use, and therefore does not carry, nor requires a 510K form. Additionally, pursuant to **Guidelines for Importation #1121**, Cell Cultures/Lines, Recombinant Cell Cultures/Lines, and Their Products (for in vitro use) (Effective October, 1998), this product does not require a USDA import permit.

The product is manufactured and produced in Canada. The animals and materials utilized in the manufacture of this product:

1. Have not been exposed to nor inoculated with any livestock or poultry disease agents that are exotic to the United States
2. Did not originate from a facility where work with exotic disease agents affecting livestock or poultry is conducted.
3. Is **non-recombinant**, non-hazardous and non-infectious, and does it contain genes or express products of exotic livestock or poultry disease agents.

Sincerely,

Anogen
Director of Operations