



ANOGEN - A Division of YES Biotech Laboratories Ltd.

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March 19, 2004

To Whom It May Concern:

In accordance with the **APHIS Animal Product Manual** (08/2003-32 PPQ, VRS), as per Table 3-8-5, Regulatory Action to Take on Recombinant Microorganisms, the following statements apply to this shipment:

The product being shipped to **company** contains the **recombinant microorganism, *Escherichia coli* (*E. coli*)** vector that expresses the human **Hepatitis C Virus polyprotein**.

The product/microorganism **does not** contain any **animal-derived additives or stabilizers**.

The product/microorganism does not contain genes or express antigens of livestock or poultry disease agents.

The product is manufactured for **in vitro general laboratory 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.

Sincerely,

Anogen
Director of Operations