

April 9, 2014

To Whom It May Concern:

In accordance with the **APHIS Animal Product Manual** (08/2003-32 PPQ, VRS), as per Table 3-8-16, Regulatory Action to Take on Monoclonal Antibodies, Ascitic Fluid, Tissue Culture Supernatants, the following statement applies to this shipment:

The product being shipped to **ABC company**, consists of **monoclonal antibodies** purified from **mouse** ascites fluid, and is directed against human **Serum Amyloid A (SAA) antigens**.

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 and **does not come from a facility where work with exotic viruses affecting livestock and avian species is conducted**.

The product is **non-recombinant**, non-hazardous and non-infectious.

Sincerely,

Hui Zheng
Director of Operations