United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Veterinary Services

4700 River Road Riverdale, MD 20737-1232

Stakeholder Import Alert: Change to VS policy for the Importation of Human and Veterinary Pharmacueticals approved by the Food and Drug Administration (FDA)

Issuance Date: November 17, 2016

Effective Date: November 18, 2016

The U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) in consultation with the Food and Drug Administration (FDA) has determined that FDA approved human and veterinary pharmaceuticals present a negligible risk for introducing foreign animal disease into the United States. Thus, these commodities may enter the United States without USDA, APHIS, VS restrictions.

A USDA APHIS VS import permit (VS Form 16-6), will not be required for FDA approved human and veterinary pharmaceuticals ready in final dosage ready for use (in bulk or packaged).

In order to facilitate correct identification of the shipment and to ensure timely delivery, USDA, APHIS,VS recommends that the following documentation or information accompanies each shipment and be presented for review by the Department of Homeland Security, Customs and Border Protection (CBP) Agriculture Specialist/Officers at the U.S. port of arrival.

For human and veterinary pharmaceuticals:

1) A written statement supplied on foreign producer/shipper letterhead which

   a) Confirms that the product being imported is approved by the FDA; and

   b) Includes a copy of the FDA-approved commercial drug product label.

OR

2) Based on information contained in shipping documents including, invoices, manifests or products labels, CBP will use information provided in the Orange Book to verify FDA approved pharmaceuticals for human use or the Green Book to verify FDA approved pharmaceuticals for veterinary (animal) use.

The guidance for vaccines for human use remain essentially the same. Vaccines for veterinary use must meet the import requirements currently in the Animal Product Manual (APM).

As a reminder, for vaccines for human use:

A written statement supplied on foreign producer/shipper letterhead which

a) Confirms that the product being imported is approved by the FDA; and

b) Confirms the human vaccine in final dosage form and packaging and intended for human use only.

c) Confirms that the product does not contain live livestock and poultry viral agents; and

d) Includes a copy of the FDA-approved commercial vaccine label.

If you have any questions about animal products and their eligibility for importation into the United States or their certification requirements, please contact National Import Export Services (NIES) at (301) 851-3300, option 1 or you can email us at: AskNIES.Products@aphis.usda.gov.

Sincerely,
National Import Export Services
Animal Products Import