



Marketing and
Regulatory
Programs

Animal and
Plant Health
Inspection Service

Veterinary Services
National Import
Export Services

4700 River Road
Unit 40
Voice 301.851.3300
Fax 301.734.8226

Stakeholder Import Alert: Change to VS policy for the Importation of Human Medical Devices Containing Animal Derived Ingredients Approved by the Food and Drug Administration (FDA)

Issuance Date: May 31, 2018

Effective Date: May 31, 2018

The U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS), in consultation with the Food and Drug Administration (FDA) has determined that FDA approved human medical devices containing animal derived ingredients present negligible risk for introducing foreign animal disease into the United States. Therefore, these commodities may now enter the United States without APHIS restrictions.

An APHIS import permit (VS Form 16-6), will no longer be required for FDA approved human medical devices containing animal origin ingredients, when the devices are in final dosage form and ready for use (in bulk form or single packaged).

Effective May 31, 2018, FDA approved human medical devices containing animal derived ingredients may be imported without an import permit as per *Guidelines for Importation of Human And Veterinary Pharmaceuticals and Vaccines, # 1100*, (https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-permits/ct_animal_imports_nopermit) if accompanied by:

a) a written statement supplied on foreign producer/shipper letterhead which confirms that the imported product is approved by the FDA; and a copy of the FDA-approved commercial drug product label.

In order to facilitate correct identification of the shipment and to ensure timely delivery, the documentation described above should accompany each shipment and be presented for review by the Department of Homeland Security (DHS), Customs and Border Protection (CBP), Agriculture Specialists/Officers at the U.S. port of arrival.

If you have questions regarding this Import Alert, please contact NIES at 301-851-3300, option 1.

Sincerely,

National Import Export Services (NIES)
Animal Products Import