Intermediate Products

APHIS does not endorse any documents for materials exported from the United States as "intermediate products" as defined in Regulation (EU) 142/2011. However, the EU requires facilities exporting intermediate products to the EU to be approved by APHIS. Exporters should contact the VS Area office serving their State for information on how to obtain these approvals. Area office contact information is available at: http://www.aphis.usda.gov/animal_health/area_offices/

Regulation (EU) 142/2011 defines an intermediate product as a derived product:

- which is intended for the **manufacture of medicinal products, veterinary medicinal products, medical devices, active implantable medical devices, in vitro diagnostic medical devices or laboratory reagents**; AND
- whose design, transformation and manufacturing stages have been sufficiently completed in order to be regarded as a derived product and to qualify the material directly or as a component of a product for that purpose; AND
- which requires some further handling or transformation, such as mixing, coating, assembling, packaging or labeling to make it suitable for placing the product on the market or putting it into service, as applicable, as a medicinal product, veterinary medicinal product, medical device, active implantable medical device, in vitro diagnostic medical device or laboratory reagent.

There is likely to be variation between EU border inspection posts (BIPs), regarding determination of which consignments qualify as "intermediate products."

Prior to export, the exporter should complete the following steps:

1. Have their importer confirm with the border inspection post (BIP) through which the product will enter the EU that the product is eligible for import with only the following documentation required: Regulation (EU) 142/2011 CHAPTER 20 "**Declaration for the import from third countries and for the transit through the European Union of intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices, in vitro diagnostics and laboratory reagents**."
2. Contact their local VS Area Office to obtain information on obtaining the relevant APHIS approval.
3. Complete the APHIS approval process.
4. Await final confirmation from the VS Area Office that the facility has been granted the relevant approval.
5. Have the importer confirm again with the BIP that all necessary information is available on Trade Control and Expert System (TRACES) and the consignment will be allowed entry with the Regulation (EU) 142/2011 CHAPTER 20 "**Declaration for the import from third countries and for the transit through the European Union of intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices, in vitro diagnostics and laboratory reagents**."