

## Export Information

The Center for Veterinary Biologics (CVB) does not require export certification for products or serials of licensed biological products leaving the country.

CVB does provide export certification, when requested, in the form of APHIS Form 2017, Official Export Certificates for Animal Biological Products and Certificates of Licensing and Inspection.

CVB is often asked about the requirements of the importing country. CVB does not maintain current knowledge on all importing requirements worldwide. Information CVB can provide to assist an exporter include the following advice:

1. Contact the Embassy of the importing country for information
2. Reference the U.S. Department of the Treasury Website ([www.treasury.gov](http://www.treasury.gov)) Resource Center to determine which countries may have trade sanctions
3. Contact the manufacturer of the product for additional information

In some cases, it is unclear why “new” import requirements are requested. When a manufacturer has attempted to resolve these issues without success, they may contact CVB, Section Leader for Inspections.

CVB will contact International Services to start a dialogue for the specific country or area. CVB and Inspection and Compliance (IC) will try to determine the source of the “new” requirement and assist in trying to resolve the issue. As this is resource intensive, resolution via this route is not fast and may not be successful. The CVB should avoid providing our International Services contacts without prior consent from our contact. Our current resource is [REDACTED], Veterinary Medical Officer at APHIS.

The inquiry to [REDACTED] should be to confirm through Veterinary Services representatives that the receiving country in question has that particular requirement.

[REDACTED]  
[REDACTED]@aphis.usda.gov [REDACTED]

### Other Situations

- A. There are approximately 33 products with the following restriction:

*Export Distribution shall be limited to authorized recipients designated by proper animal health regulatory officials – under such additional conditions as these authorities may require.*

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Compliance with this restriction can be monitored as follows:

1. On-site inspection review of distribution records
2. Written requests to CVB Policy, Evaluation, and Licensing (PEL) Reviewer for each shipment which includes:
  - a. Information from importing country
  - b. Product code and serial number
  - c. Amount of inventory to be exported – the Reviewer validates enough doses have been released via the LSRTIS Serial Search function
3. Written request to the PEL Reviewer to include this information in Section VI of the Outline of Production (OP)
  - a. Information from the importing country
  - b. PEL Reviewer responds with a letter allowing shipments to the country or countries and requests this information be added to the OP

If IC receives a request for a product that has this restriction, it is processed and compliance is monitored through on-site inspections.

### **B. FDA Export Reform and Enhancement Act of 1996 – see Veterinary Services Memorandum No. 800.94**

1. Allows the export of unlicensed veterinary biological products
2. Drug/device must comply with the law of the importing country
3. Company has a marketing authorization from importing country
4. Product prepared by GMP or equivalent standards
5. Importing country must have competent regulatory authorities
6. Product is not presented (labeled) as U.S. licensed Veterinary Biological Product