How to import medical devices into the US

Planning a meeting is always a challenge, but facing with medical meetings and the import or export of devices for exhibitions with international exhibitors in the US sometimes seems impossible because of the federal regulations.

The **Customs and Border Protection** (CBP) and the **Food and Drug Administration** (FDA) are the organisms that regulate the entry of many types of devices, radiation-emitting products and blood. It is important to know that these regulations are made to protect the public, but is a well-known fact that this affects directly the process for the exhibitors in aspects like documentation, importing procedures and lead times required.

First of all, as many other importations, **you have to get prepare for customs clearance** by following the checklist of recommendations from the CBP o asses the duties and taxes due:

- **Official documentation showing date and location of the Trade Show**
- **Confirmation that you are an exhibitor**
- **Documentation indicating value of items**
- **Mark items "Not for Sale" or mutilate the items**
- **Contact the Port of Entry prior to travel**
- **Complete CF7523-"Entry and Manifest of Merchandise free of Duty" (For NAFTA Items only)**
- **Check with for any possible restrictions or required documentation**
- **Obtain the HTSUS code for your items**

Generally the CBP clearance involves a number of steps: entry, inspection, appraisement, classification, and liquidation. But in the case that the items require it, **you have to be prepared for a FDA clearance** too. It means that you have to comply with applicable U.S. regulations before, during, and after importing into the U.S. or its territories; this is because the **FDA does not recognize regulatory approvals from other countries.**

Foreign Manufacturers

For foreign manufacturers, these requirements include **registration of establishment, listing of devices, manufacturing in accordance with the quality system regulation, medical device reporting of adverse events**, and Premarket Notification 510(k) or Premarket Approval, if applicable. In addition, the foreign manufacturers must designate a **United States agent**. Also, foreign manufacturing sites are subject to FDA inspection.

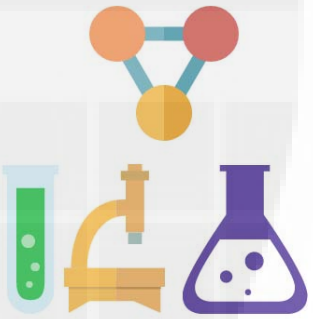
Products that emit radiation

When you need to export electronic products that emit radiation, you have to fulfill some requirements that include performance **standards, labeling, and submission of radiation safety product reports**. Guidance on these requirements can be found on the Internet under Electronic Product Radiation Control. When manufacturers submit radiation safety product reports, the reports are entered into a database and assigned an accession number (file point). **Importers may submit radiation safety product reports on behalf of manufacturers.**

Avoidance **Behavior** **Control**

Blood Products

The Center for Biologics Evaluation and Research (CBER) is the one in charged for the regulation of biological and related products -including blood, blood products and cellular products- . Foreign firms which manufacture this kind of products must comply with applicable FDA requirements before, during, and after importing into the United States. This includes the **name of the US agent, the name of each importer/exhibitor, and each person who imports or offers for import the blood products** must also be provided.



Import Process

1. All medical devices that are imported into the U.S. must meet CBP requirements in addition to FDA.

2 Importers of radiation emitting electronic products subject to a federal performance standard are required to submit a written declaration on "Declaration of Products Subject to Radiation Control Standards," form FDA-2877, along with other import entry information, including accesssion number, if appropriate, through CBP to the appropriate FDA district office.

3 When an entry is filed with CBP, a copy of the entry is also provided to the local FDA district office. The FDA district office then determines if the product complies with FDA requirements.

4 Upon entry, FDA may examine certain devices to assure their safety and effectiveness. When this occurs, FDA will issue a notice to the importer of a record on a form titled "Notice of FDA Action." Sampling may involve examining the product at the port of entry or physical collection of a statistical portion of the lot for analysis by an FDA laboratory.

It is important to notice that if you want to send medical devices to the US, you must pay an annual registration fee electronically at the Device Facility User Fee (DFUF) website. Take into consideration that the process to obtain your Payment Confirmation Number (PCN) by email once your payment has cleared can take several days, so be sure to make payment at least a few days before registering.

Using ATA Carnet

Please remember that you have to accomplish with all the regulations needed for your items (even if the entry is permanent and not temporary), unless you prefer to use an ATA Carnet to simplify this process. If this is your choice, take into consideration that the carnet does not cover blood products and other perishables.

The Expert Advice

Working side by side with an expert will make things easier for you in such a tricky issue like the regulations shown above. Exhibitions Cargo is a company specialized in meetings and exhibitions that will help you in the whole process, from the appropriate advice to obtain all the certifications required to the arrival of your items to the venue.

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