GLOBAL VIEW notes

ROGERS WORLDWIDE

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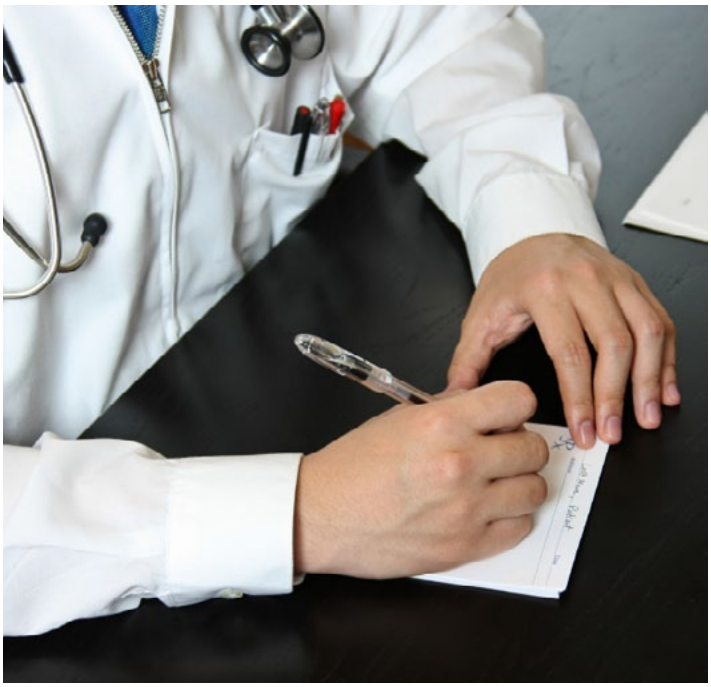
The Right Prescription for International Medical Exhibitors

by Michelle Bruno



Almost any discussion about medical trade shows involves the impact of federal regulations. For example, As of August 1, 2013, the Sunshine Act (part of the Affordable Healthcare Act) requires that meeting planners and exhibition organizers track all transfers of value over $10—food, meeting materials, travel, lodging, entertainment, gifts, honoraria—given to doctors and teaching hospitals.

For exhibitions with international exhibitors, there is even more to discuss. U.S. Customs and Border Protection (CBP) and the Food and Drug Administration (FDA) have established regulations to protect the public. These rules also affect the documentation, importing procedures and lead-time required by exhibitors to import many types of devices, radiation-emitting products and blood.

While much has been written about Sunshine Act compliance, little has been published about the hoops that international exhibitors have to jump through in order to deliver their products to medical shows in the U.S. This issue covers the requirements and how to avoid the most common "hiccups" that exhibitors experience.

Preparing for customs clearance

As with most importations, exhibitors must prepare a commercial invoice listing the items in detail and assigning a value for commercial purposes. This is required for CBP to assess the duties and taxes due. If the items also require FDA clearance, CBP will look for proof that the shipment complies with FDA regulations as well.

Importing medical devices

Foreign manufacturers have to comply with a number of medical device regulations in order to import products into the U.S. The requirements include registration of the manufacturing facility, 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,

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foreign manufacturers must designate a United States agent. Foreign manufacturing sites are also subject to FDA inspection.

Proof of compliance for the FDA

Medical shipments must be accompanied by documentation that proves the devices or products are in compliance with FDA regulations. By submitting Affirmation of Compliance (AofC) codes (a voluntary process), an exhibitor can expedite the entry review process and increase the likelihood that the company's shipment will move through the clearance process more quickly avoiding a more time-consuming FDA review.

Importing radiation-emitting products

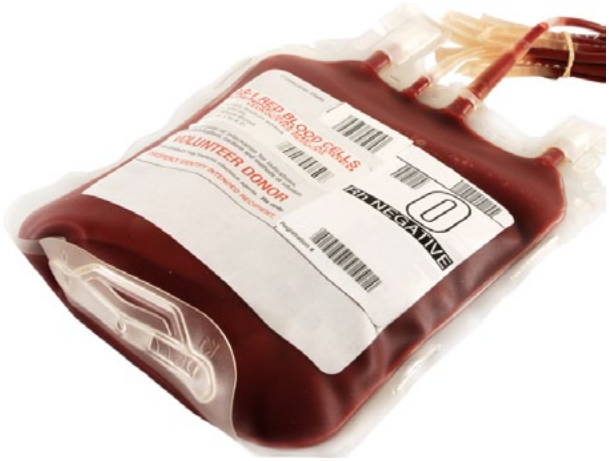
Foreign devices that emit radiation—from tanning beds to MRIs (magnetic resonance imaging) to mammogram units—must meet FDA requirements prior to import. Foreign manufacturers are subject to performance standards, labeling, and submission of radiation safety product reports. When manufacturers submit radiation safety product reports, the reports are entered into a database and assigned an ***accession number***, which is required for importation.

Importing blood products

Blood establishments located outside of the United States that import or offer for import blood products into the U.S. are required to register with the FDA. The name of the United States agent, the name of each importer/exhibitor, and each person who imports or offers for import the blood products must also be provided.

Avoiding some of the hiccups

There are some common mistakes and omissions that exhibitors make. By following the four-step process below, exhibitors can avoid some of the major delays experienced by first-time importers:



1. All medical device shippers/exhibitors who intend to send medical devices to the U.S. must pay an annual user fee to the FDA.
2. Then, the medical device shipper/exhibitor must register with the FDA as a medical device establishment and be able to prove ***active registration***.
3. Next, each medical device or part thereof must have a medical device listing number.
4. And finally, if the medical device emits radiation as defined by the FDA, then the item must have an accession number.

Bypassing the requirements

The requirements for importing medical devices must be met regardless of the type of entry (permanent or temporary) made unless an ATA Carnet covers the non-compliant goods. Under the provisions of carnet use, products MUST be re-exported. Blood products and other perishables are not appropriate for carnets.

Working with an expert

The import regulations for medical devices and fluids can be complex. Allowing extra time in the import process to obtain the appropriate certifications and registrations is the first step. Working closely with a freight forwarder and customs broker that has expertise in importing medical products for exhibitions can make the process easier.

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