



“TOP TIPS WHEN IMPORTING MEDICAL DEVICES TO ENSURE COMPLIANCE”

1. Medical Device Importation Checklist:

- a. Assure you know what Class your medical device is. I, II or III?
- b. Does the manufacturer have a valid Establishment Registration?
- c. Does the initial importer have a valid Establishment Registration?
- d. **Use the Search Database** - <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>
- e. Is there a valid Device Listing in place?
- f. For Class II devices, is a 510k (Pre-Market Notification) necessary?
- g. For Class III devices, is a PMA (Pre-Market Approval) necessary?
- h. Review and assure compliance with Labeling Requirements.
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=801>
- i. Review and assure compliance with Good Manufacturing Practices/Quality System Regulation.
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=820>

2. Protect your own Intellectual Property Rights (IPR).

- a. Register your trademark with the U.S. Patent and Trademark Office (www.USPTO.gov)
- b. Record your trademarks with CBP - <https://apps.cbp.gov/e-recordsations/>
- c. For \$190 U.S. Customs Will Police Your Brand -
http://customsandtradelaw.blogspot.com/2007/07/why-record-trademarks-and-copyrights_24.html

3. Keep records proving you used Reasonable Care. – Request a binding ruling from CBP!

- a. **Importing into the U.S.: A Guide for Commercial Importers** (Includes a reasonable care checklist) - <http://cbp.gov/linkhandler/cgov/newsroom/publications/trade/iius.ctt/iius.pdf>

4. Confirm you're using the correct Harmonized Tariff Schedule (HTSUS)

- a. **Harmonized Tariff Schedule** – <http://www.usitc.gov/tata/hts/bychapter/index.htm>
- b. **Customs Rulings Online** - <http://rulings.cbp.gov/>

5. Confirm you're using the correct value for your product, do you use related parties?

6. Confirm you're using the correct Country of Origin. Do you source products from many countries?

7. If you receive a Notice from the U.S. Food and Drug Administration (FDA) or U.S. Customs and Border Protection (CBP) – **IMMEDIATELY** consult an expert to answer thoroughly.

- a. If you receive a Notice of FDA Action, assure you respond in a timely basis and request extensions!
- b. If you receive a Warning Letter from the FDA, assure you consult an expert and respond within 15 days.
- c. If you are receive notification that you are on an Import Alert List, take action through an expert to be removed.
- d. If you receive a notice of detention or seizure notice from CBP, be PROACTIVE.
- e. Always Petition **Penalties and Liquidated Damages** Claims.
- f. **U.S. Customs Seized my merchandise, now what?** -
<http://customsandtradelaw.blogspot.com/2012/02/us-customs-border-protection-seized-my.html>

ADDITIONAL RESOURCES FOR IMPORTING:

- **Customs & International Trade Law Blog** - <http://www.customsandinternationaltradelaw.com>
- **CBP Basic Importing and Exporting** - http://www.cbp.gov/xp/cgov/trade/basic_trade/
- **CBP's Legal Decisions/Publications** - <http://www.cbp.gov/xp/cgov/trade/legal/>
- **FDA - Warning Letter List** -
<http://www.fda.gov/iceci/enforcementactions/warningletters/default.htm>
- **FDA - Import Alert List** - <http://www.fda.gov/forindustry/importprogram/importalerts/default.htm>
- **FDA – Regulatory Procedures Manual** –
<http://www.fda.gov/iceci/compliancemanuals/regulatoryproceduresmanual/default.htm>
- **FDA – Device Advice** - <http://www.fda.gov/medicaldevices/deviceregulationandguidance/default.htm>



Jennifer Diaz, Esq.
Chair, Customs and International Trade Department
Becker & Poliakoff, P.A.
(305) 260-1053 (office)
(305) 724-3281 (cell)
jdiaz@bplegal.com