Regulatory Alert: FDA Amends Regulations for Medical Device Registration and Listing Requirements

On August 2, 2012, FDA published a final rule amending regulations to meet statutory amendments to the device registration and listing provisions of the Federal Food, Drug and Cosmetic Act as amended by the Food and Drug Administration Amendments Act of 2007 requiring electronic submission. This final rule also facilitates FDA collection of additional registration information in order to comply with the Bioterrorism Act of 2002.

The final rule requires electronic submission of foreign and domestic establishment registration and device listing information unless FDA grants a waiver and the inclusion of additional information identifying certain parties involved in the importation of the foreign establishment’s devices into the U.S. FDA’s Unified Registration and Listing System (FURLS), internet-based system is used to electronically receive this data and has been operational since October 2007. This final rule is effective October 1, 2012.

What are the significant changes?

- **Electronic Submission:** Domestic and foreign medical device establishments must submit registration and listing information electronically to FDA through the FDA Unified Registration and Listing System (FURLS). FDA noted that device establishment owners/operators have been actively using FURLS since October 1, 2007. Use of this system will improve the process of submitting registration and listing information and provide faster access to the required information.

- **Additional Information:** Domestic and foreign medical device establishments must provide email addresses for the establishment’s official correspondent and owner-operator and the website universal resource locator (URL). Although this information is currently collected it hasn’t been a requirement.

- **Updates/Changes to Registration Information:** Medical device establishments are required to update registration information within 30 days of registration information changes. Establishments will have the ability to access and edit registration information online eliminating hardcopy manual submissions.

- **Information from Foreign Establishments:** Foreign medical device establishments whose medical devices are imported or offered for import to the United States must identify all importers known to them and provide the name of each person who imports or offers to import their device into the U.S. Specific definitions for these two new categories are covered in 21CFR Part 807.3.

- **Elimination of Exemptions:**
  - Contract Manufacturers and Contract Sterilizers are required to register their establishments and list their devices.
  - Foreign establishments with devices that enter a foreign trade zone and re-export from the FTZ without entering the U.S. commerce are required to register and list their devices.
  - Foreign establishments with devices imported under the import for export (IFE) provision are required to register and list their devices.
What is required?

1. Air Waybill (AWB) and detailed Commercial Invoice to include:
   - Complete medical device manufacturer name and address
   - FDA Product Code and applicable device Affirmation of Compliance Codes with Qualifier Numbers (if applicable)
   - AoIC = Device Foreign Manufacturer Registration Number (DEV)
   - Device Foreign Exporter Registration Number (DFE)
   - Device Initial Importer Registration Number (DII)
   - Investigational Device Exemption Number (IDE)
   - Device Listing Number (LST) \textit{LST is the medical Device Listing Number assigned by the US FDA to the actual manufacturer for the specific finished Medical Device.}
   - Device Premarket Approval Number (PMA)
   - Device Premarket Notification Number-510(k) (PMN)
   - Model Number-Manufacturer’s model/catalog number for the product (MDL)
   - Impact Resistance Lens Certification (IRC)
   - Radiation Emitting Electronic Products Subject to Radiation Control Standards require the Form FDA 2877 Declaration including the Radiation Health Accession Number (ACC) or (ANC)

2. Letter to Industry about Import Entry Review Process (March 24, 2011)

3. Letter to Industry about Import Entry Review Process (September 6, 2011)

U.S. and Foreign Medical Device establishments will benefit from the electronic system submissions as the data will be available real time and eliminate the burdensome exchange of paper filings.

U.S. and Foreign Medical Device establishments should be aware of this FDA regulatory change and the importance of maintaining accurate information in FDA/FURLS. If the device establishment owner doesn’t have an account they need to establish one with FDA. FURLS have been operational since October 1, 2007 and establishment owners have been using the system. Failure to keep information updated and accurate may lead to import clearance delays for the medical device(s).

Advisory References:

- Medical Device Establishment Registration and Listing - Notice of Changes for FY 2013. August 2, 2012 letter
  http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm314844.htm

- FAQ’s about the New Device Registration and Listing Requirements
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm318796.htm

- FDA Overview of Device Regulation
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm

- Medical Devices, “Does the Product Emit Radiation?”
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice