Medical Device Establishment Registration and Listing - Notice of Changes for FY 2013

U.S. Food & Drug Administration

August 2, 2012

Dear Medical Device Establishments:

This letter is to advise you of changes to the requirements for registration and listing of medical devices that will take effect on October 1, 2012.

These changes are required as a result of the enactment of new FDA legislation (FDA Safety and Innovation Act [FDASIA] and the publication of the revised Title 21 CFR, Part 807 on August 2, 2012).

Starting in Fiscal Year (FY) 2013, which begins on October 1, 2012, all registered medical device establishments are required to pay the annual registration fee, regardless of establishment type or activities conducted. In addition, certain establishments must comply with additional registration and listing requirements.

The table below summarizes the requirements based on the type of medical device establishment required to register and list.

FY2013 Requirements for Registration and Listing by Establishment Type

Establishment Type	**Requirement for FY2013**
All Establishments – Both Foreign And Domestic	Pay the annual registration user fee prior to registration.
Domestic	
All Establishments, Except Initial Importers	Identify all proprietary names for each device listed. Names may be marked as confidential to exclude them from the data published on the FDA web site if disclosure could identify confidential business relationship(s). Proprietary names may be uploaded from Excel spreadsheets rather than manually typed, if preferred.
	Identify combination products and the type of combination product (e.g., device/drug, device/biologic) during listing.
Initial Importers	Identify manufacturers of products being imported. This may be done by listing number or searching and identifying the

	manufacturer in FURLS.
Contract Manufacturers	Register and list, regardless of whether the contract manufacturer puts the device into commercial distribution or returns the device to their customer.
	For non-exempt devices, list only after the manufacturer, specification developer, single-use device remanufacturer or remanufacturer has done so.
Contract Sterilizers	Register and list, regardless of whether the contract sterilizer puts the device into commercial distribution or returns the device to their customer.
	For non-exempt device, list only after the manufacturer, specification developer, single-use device remanufacturer or remanufacturer has done so.
Manufacturers, Specification Developers, Single-Use Device Manufacturers, Remanufacturers, Relabelers	For non-exempt devices, list prior to contract manufacturer or sterilizer, if one is used.
Complaint File Establishment	Register and list as a new establishment type and identify facility who maintains complaint files only (per 21 CFR 820.198).
Establishments Located in Foreign Trade Zones	Register and list.
	Identify the establishment as located in a foreign trade zone.
Foreign	
All Establishments	Identify all proprietary names for each device listed. Names may be marked as confidential to exclude them from the data published on the FDA web site if disclosure could identify confidential business relationship(s). Proprietary names may be uploaded from Excel spreadsheets rather than manually typed, if preferred.
	Identify combination products and the type of combination product (e.g., device/drug, device/biologic) during listing.
	Identify all importers known to the foreign establishment, including agents, brokers, or other parties used by the foreign establishment to facilitate the

	import of its device into the United States.
Manufacturers, Specification Developers, Single-Use Device Manufacturers, Remanufacturers, Relabelers	For non-exempt devices, list prior to contract manufacturer or sterilizer, if one is used.
Complaint File Establishment	Register and list as a new establishment type and identify facility who maintains complaint files only (per 21 CFR 820.198).
Contract Manufacturers	For non-exempt devices, list only after the manufacturer, specification developer, single-use device remanufacturer or remanufacturer has done so.
Contract Sterilizers	For non-exempt devices, list only after the manufacturer, specification developer, single-use device remanufacturer or remanufacturer has done so.

Summary of Recent Legislative and Regulatory Changes Impacting Medical Device Registration and Listing

- **Passage of the FDA Safety and Innovation Act (FDASIA)**
  The FDA Safety and Innovation Act (FDASIA) was signed into law on July 9, 2012. This law includes the Medical Device User Fee Amendments of 2012 (MDUFA III) as well as other medical device provisions. These provisions affect the standard for FDA approval of clinical trials, provide an alternative de novo review pathway for risk-based classification of devices, expand FDA's postmarket surveillance capabilities, shorten timelines for scheduling appeals meeting and issuing decisions, and change the process for reclassification of devices.

- **Re-authorization of User Fees per Medical Device User Fee Amendments of 2012 (MDUFA III)**
  The Medical Device User Fee Amendments of 2012 (MDUFA III) were enacted as part of FDASIA. MDUFA III will take effect on October 1, 2012 and will sunset in five years on October 1, 2017. MDUFA III mandates that an annual registration user fee be paid for all types of establishments. The fee for FY2013 is $2,575. For more information about User Fees and MDUFA III see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/default.htm [1].

- **Revised Title 21 of the Code of Federal Regulations (CFR), Part 807, Establishment Registration and Device Listing Regulations**
  On August 1, 2012, FDA published the revised version of Part 807 to reflect the statutory amendments to the device registration and listing provisions of

the Federal Food, Drug, and Cosmetic Act (FD&C Act). The statutory amendments include requiring domestic and foreign device establishments to submit their registration and device listing information electronically via the FDA Unified Registration and Listing System (FURLS) Device Registration and Listing Module (DRLM) and specifying the timeframes when establishments are required to submit such information. The revised regulations facilitate collection of additional registration and listing information from foreign establishments and initial importers as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) and the Food and Drug Administration Amendments Act of 2007. It also updates certain provisions in Part 807 to improve the quality of registration and listing (R&L) information available to FDA.

We hope you find this information beneficial as you understand your requirements and responsibilities regarding registration and listing. If you have any questions or need assistance regarding registration and listing, please contact the Centers for Devices and Radiological Health (CDRH) Registration and Listing Helpdesk by email at reglist@cdrh.fda.gov [2].

Sincerely yours,

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Links:
[1] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/default.htm
[2] http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/mailto:reglist@cdrh.fda.gov