Registration and Listing

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Regulatory Authority

- Section 510 of the Food, Drug and Cosmetic Act as amended requires establishment registration and device listing
- Regulation - Revised 21 CFR Part 807 published in Summer 2012
- The Food and Drug Administration Safety and Innovation Act (FDASIA) requires all establishments to pay the annual registration user fee

Electronic Registration and Listing

- FDA Unified Registration and Listing System (FURLS) Device Registration and Listing Module (DRLM) launched on October 1, 2007
  - Web-based entry of R&L information
  - All establishments must register and list electronically (on-line) unless waiver granted
  - Congress established the schedule of annual registration user fees in FDASIA
  - No reduction in fee for small groups or businesses

Electronic Registration and Listing

- Annual registration October 1 – December 31st of each calendar year
- Listings must be updated during annual registration
- Non-exempt products must be listed by their 510(k), PMA, HDE or NDA number
- Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products (807.39)

General Problems/Issues

- Firms cannot remember their account ids or passwords for systems
- Firms pay but do not complete annual registration
- Firms attempt to register and list before paying
- Firms wait to register until end of calendar year
- Firms allow registration to lapse and devices get detained

Registration Requirements

- Initial domestic establishment registration within 30 days of starting commercial distribution of a device
  - Pay the annual registration user fee
  - Register establishment
  - Must create at least one listing/identify one product at time of initial registration
- Initial importers are not required to submit listings but must identify manufacturers of the products they import

Registration Requirements

- Prior to their devices being imported or offered for import to the United States, foreign establishments must:
  - Pay the annual registration user fee
  - Register their establishment
  - Create at least one listing/identify one product at time of initial registration
  - Identify anyone known to them who imports their product or offers their product for import
  - Identify a United States agent

Foreign Establishment Requirements
United States Agent

- All foreign establishments must:
  - Appoint a **single** United States agent and identify the agent separately to each Center
- United States agent must reside or have a physical place of business in the United States - no Post Office boxes or mail drops allowed
- United States agent does not register

Foreign Establishments
U.S. Agent Responsibilities

- Assist FDA with scheduling of inspections
- Assist FDA with communications
- Accept information/documents that FDA is unable to provide to the foreign establishment
- Respond to questions concerning products being imported or offered for import
- May act as Official Correspondent if so designated by the foreign establishment

Device Listing Requirements

- All exempt devices under one product code have only one listing (not each model, catalog number, brand name)
- Non-Exempt Products – the correct product codes are displayed after the user enters the 510(k), Denovo, PMA, NDA, HDE or PDP number
- Identify all proprietary or brand names under which the product is marketed in the U.S.

Changes Beginning Fiscal Year 2013 (FY2013)

- All establishments must pay the annual registration user fee
- Proprietary Names are required
  - User can upload from Excel spreadsheet
  - Names that would identify relationships can be marked confidential
- Importers must identify manufacturers of products imported
- Foreign exporting or offering for export must identify all importers “known to them”
  - Users can upload from Excel spreadsheet

Changes Beginning Fiscal Year 2013 (FY2013)

- All contract manufacturers and sterilizers required to register and list
  - Not just those who put devices into commercial distribution
- When combination products are listed, must identify the type of combination (device/drug, device/biologic, etc.)
- Product must be listed by manufacturer or spec developer before contract manufacturer or sterilizer can list
- Complaint handler establishment type added

What Information Will I Need to Use FURLS DRLM?

- The owner's business name, address and contact information (including email address)
- The name, address and contact information (including email address) of the person who will be your official correspondent
  - Can be the same as your owner information
- Foreign only
  - The name, address and contact information (including email address) of your US agent

What Information Will I Need?

- The name and address of the establishment you are registering
- For devices that are exempt from premarket clearance or approval:
  - Product code for the device (can be identified during FURLS DRLM session)
  - What activity is performed at the establishment for the device (manufacture, relabel, etc.)
  - The proprietary or brand names that the device is marketed under

What Information Will I Need?

- For devices that require FDA clearance or approval:
  - The submission number from your clearance or approval letter (K123456, DEN123456, P123456, N12345, etc.)
  - What activity is performed at the establishment for the device (manufacture, relabel, etc.)
  - The proprietary or brand names that the device is marketed under
- Foreign only – all devices exported to the U.S.
  - The registration number of any registered importer
  - Name and address of any non-registered importer

What Information Will I Need?

- Initial importers only must identify the manufacturer of the product(s) they import
  - Listing number
  - Registration number
  - Name or address information
- If you are the specification developer or repack or relabel the product you import, you should not identify yourself as an initial importer for that product

What Information Will I Need?

- As of Fiscal Year 2013, all registered establishments must pay the annual registration user fee and obtain a Payment Identification Number (PIN) and Payment Confirmation Number (PCN)

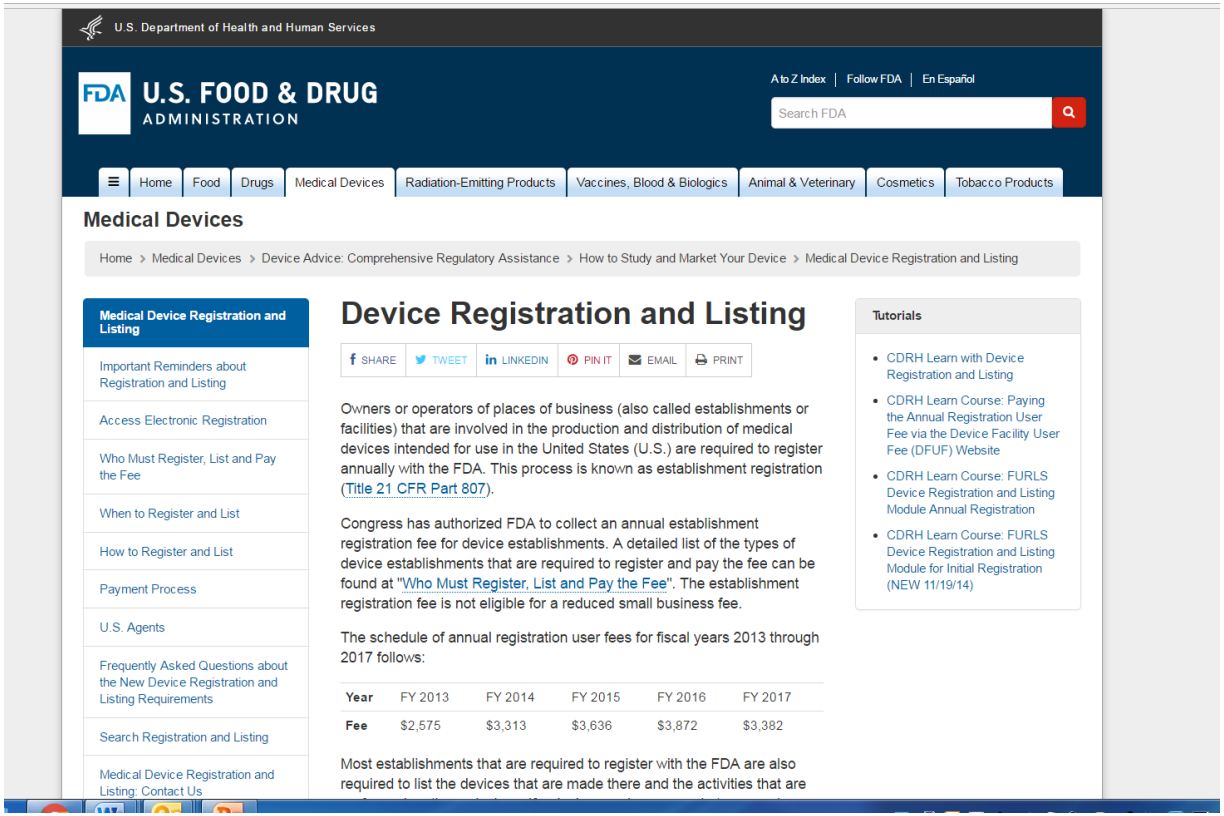
You will need your PIN and PCN to complete your registration.

You will not be allowed to complete your registration without your PCN.

Mechanisms for Viewing

- **Public R&L Database**
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
  - Updated once a week; displays active establishments and listings only
- Within FURLS DRLM:
  - Search choice from main menu
  - Download of listing data

Registration and Listing Home Page -



http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm

Sources of Registration and Listing Information

1. Registration and Listing and FURLS Information - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm
2. Establishment Registration (part of Device Advice) - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm
3. Medical Device Listing (part of Device Advice) - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm#list

Sources of R&L Info

4. Releasable Establishment Registration and Device Listing Files for download - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053199.htm
5. Product Code Classification Database - http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
   - Firms use to search for product code for exempt listing

Sources of R&L Info

6. “Who Must Register, List and Pay Fee” - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm

Device Facility User Fee (DFUF) Website

- For questions and guidance regarding this website, we recommend you call them at: 301-796-7200 or e mail them at: userfees@fda.gov .
- Once you have received your Payment Identification (PIN) and Payment Confirmation Number (PCN) you can proceed to complete the registration process in FURLS.

Registered, Active At End FY16

- **Domestic Firms**
  - About 13,502 firms registered
  - 3,294 of them are initial importers only
- **Foreign Firms**
  - About 12,067 firms registered

Firms R&L Contact Info

- E-mail is best way for firms to contact us:
  - Assistance with annual registration process or FURLS/DRLM: reglist@cdrh.fda.gov
  - Assistance with policy questions and import detention issues: device.reg@fda.hhs.gov

- Phone number:
  - 301-796-7400
    - Option 1 for help with FURLS/DRLM
    - Option 2 for help with detention or policy issues