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 - 21 CFR Part 807, subparts A-D
- The Food and Drug Administration Amendments Act of 2007 (FDAAA) mandated use of electronic system and introduced annual registration user fee for many types of establishments
- Revised 21 CFR 807 is expected to be published in Summer 2012

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
  - 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, IND 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 that are required to pay 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, if required
  - Register their establishment
  - Must create at least one listing/identify one product at time of initial registration
- Initial distributors not required to submit listings

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, if required
  - Register their establishment
  - Must create at least one listing/identify one product at time of initial registration
  - 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), PMA, NDA, HDE or PDP number
- Although system allows entry of multiple proprietary names, this information is not mandatory

Upcoming Changes to 21 CFR 807

- Proprietary Names will be required
  - User can now 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
- All contract manufacturers and sterilizers required to register and list
  - Not just those who put into commercial distribution
- Combination Product flag

Other Pending Changes

- Product must be listed by manufacturer or spec developer before contract manufacturer or sterilizer can list
- Complaint handler flag or establishment type

Device Listing Requirements

- All foreign establishments, regardless of type, are required to list
  - Examples: manufacturer that ships to US; contract manufacturer or sterilizer that ships to foreign exporter; foreign exporter
- Any firm required to register also has to list with the exception of initial distributors/importers
- Specification developers have to list even if they are using a contract manufacturer or contract sterilizer

Independent Firms That Offer Registration and Listing Services

- Please be aware that various firms offer their services to assist both domestic and foreign establishments with registration and listing
- These firms are not affiliated with FDA and FDA has not contracted with any organization
- Any fees paid to these firms are not part of the registration user fees

Registered for FY11

- **Domestic Firms**
  - About 13,881 firms registered
  - 4,972 of them are initial importers only
- **Foreign Firms**
  - About 10,062 firms registered

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 (optional)

What Information Will I Need?

- For devices that require FDA clearance or approval:
  - The submission number from your clearance or approval letter (K123456, P123456, N12345, etc.)
  - The product codes, if any, that were shown on your clearance or approval letter
  - What activity is performed at the establishment for the device (manufacture, relabel, etc.)
  - The proprietary or brand names that the device is marketed under (optional)

What Information Will I Need?

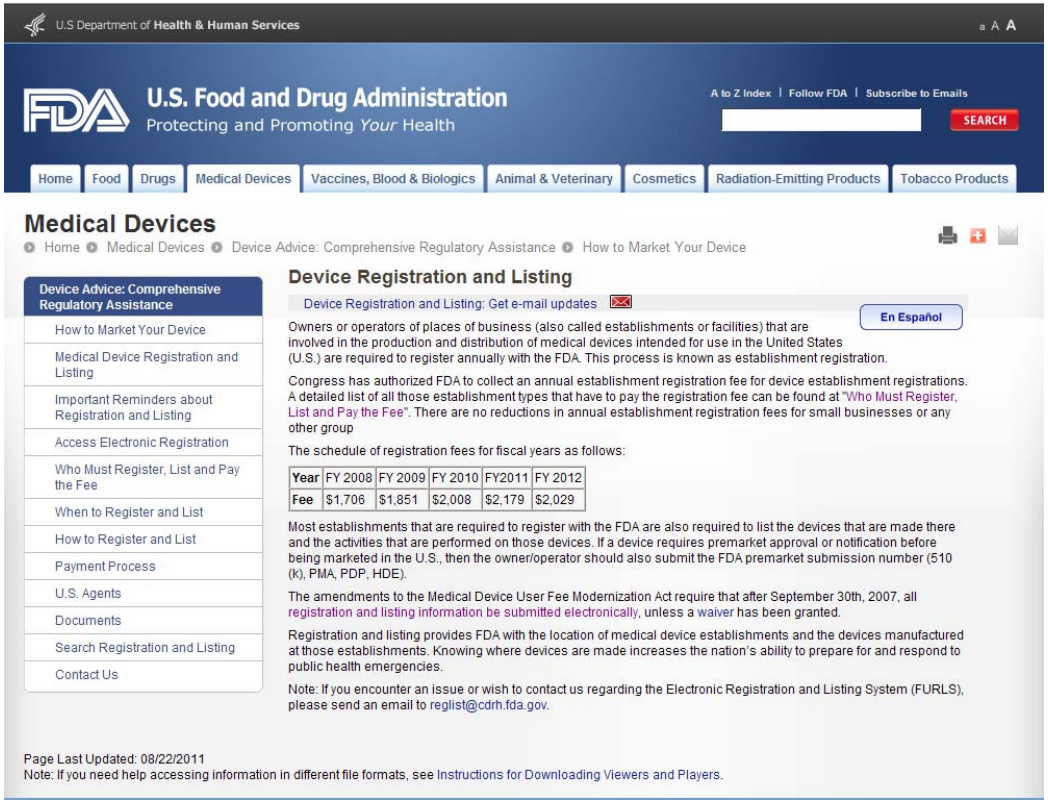
- If your facility does any of the following you must pay the annual registration user fee and obtain a Payment Identification Number (PIN) and Payment Confirmation Number (PCN):
  - Manufacture
  - Manufacture and distribute for another party
  - Sterilize and distribute for another party
  - Reprocess single-use devices
  - Develop specifications for manufacture by another party
  - Manufacture a device for export only

You will need your PIN and PCN to complete your registration

Mechanisms for Viewing

- **Public R&L Database** http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
  - Updated once a week; displays active firms only

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 PIN/PCN number you may proceed to complete the registration process in FURLS.

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