

# Registration and Listing

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04/25/2011

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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 31<sup>st</sup> 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 -

The screenshot shows the FDA website's 'Medical Devices' section, specifically the 'Device Registration and Listing' page. The header includes the FDA logo and navigation links. The main content area features a sidebar with a table of contents, a 'Device Registration and Listing' section with an 'En Español' button, and a table of registration fees for fiscal years 2008-2012. The page footer contains update information and a note about file formats.

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## Medical Devices

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### Device Advice: Comprehensive Regulatory Assistance

- How to Market Your Device
- Medical Device Registration and Listing
- Important Reminders about Registration and Listing
- Access Electronic Registration
- Who Must Register, List and Pay the Fee
- When to Register and List
- How to Register and List
- Payment Process
- U.S. Agents
- Documents
- Search Registration and Listing
- Contact Us

### Device Registration and Listing

Device Registration and Listing: Get e-mail updates [En Español](#)

Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to register annually with the FDA. This process is known as establishment registration.

Congress has authorized FDA to collect an annual establishment registration fee for device establishment registrations. A detailed list of all those establishment types that have to pay the registration fee can be found at "[Who Must Register, List and Pay the Fee](#)". There are no reductions in annual establishment registration fees for small businesses or any other group.

The schedule of registration fees for fiscal years as follows:

Year	FY 2008	FY 2009	FY 2010	FY2011	FY 2012
Fee	\$1,706	\$1,851	\$2,008	\$2,179	\$2,029

Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices. If a device requires premarket approval or notification before being marketed in the U.S., then the owner/operator should also submit the FDA premarket submission number (510(k), PMA, PDP, HDE).

The amendments to the Medical Device User Fee Modernization Act require that after September 30th, 2007, all registration and listing information be submitted electronically, unless a waiver has been granted.

Registration and listing provides FDA with the location of medical device establishments and the devices manufactured at those establishments. Knowing where devices are made increases the nation's ability to prepare for and respond to public health emergencies.

Note: If you encounter an issue or wish to contact us regarding the Electronic Registration and Listing System (FURLS), please send an email to [regist@cdrh.fda.gov](mailto:regist@cdrh.fda.gov).

Page Last Updated: 08/22/2011  
Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

<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](mailto: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](mailto:reglist@cdrh.fda.gov)
  - Assistance with policy questions and import detention issues: [device.reg@fda.hhs.gov](mailto: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