



# Device Establishment Registration & Listing

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# Device Establishment Registration and Listing

## What we will cover:

1. Regulatory Requirements
2. Who Is Required To Register and List
3. When to Register and List
4. Registration and Listing Information
5. FURLS
6. User Fees

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# Regulatory Requirements

- **Section 510 of Food, Drug and Cosmetic Act (FD&C Act)**
  - enacted in 1976, since amended
  - required medical devices establishments to register and list
  - devices manufactured, prepared, propagated, compounded, assembled or processed
- **Food and Drug Administration Amendments Act (FDAAA)**
  - enacted in September 2007
  - mandated an FDA electronic registration and listing system
  - introduced required user fees for many establishment types

# Regulatory Requirements

- **Food and Drug Administration Safety and Innovation Act (FDASIA)**
  - enacted July 2012
  - expanded user fee requirements to all establishment types
  
- **21 CFR Part 807, revised**
  - published August 2, 2012
  - regulation to interpret law
  - explains specific regulatory registration and listing requirements

# Regulatory Requirements

## **Title 21 Part 807- Establishment Registration and Device Listing For Manufacturers and Initial Importers of Devices**

A: Definitions

B: Procedures for Device Establishments

C: Procedures for Foreign Device Establishments

D: Exemptions

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# Who Is Required to Register

## Domestic

- Manufacturers/Remanufacturers
  - Kit Assemblers
- Repackagers/Relabelers
- Contract Manufacturers/Sterilizers
- Specification Developers
- Reprocessors of Single Use Devices
- Complaint Handlers
- Initial Importers (Initial Distributors)
- note - in contrast Domestic Distributors do not register



# Who Is Required to Register

## Foreign

- Manufacturers/Remanufacturers
  - Kit Assemblers
- Repackagers/Relabelers
- Contract Manufacturers/Sterilizers
- Specification Developers
- Reprocessors of Single Use Devices
- Complaint Handlers
- Foreign Exporters and Private Label Distributors
- **note – applies only if devices are sold in the United States**

# Who Is Required to Register

Establishment Type	Domestic	Foreign
Manufacturer / Remanufacturer / Kit Assemblers	Yes	Yes
Specification Developer	Yes	Yes
Contract Manufacturer / Sterilizer	Yes	Yes
Repackagers / Relabelers	Yes	Yes
Reprocessors of Single Use Devices	Yes	Yes
Complaint Handlers	Yes	Yes
Initial Importers	Yes	No

# Exemptions from R&L Requirements

- Component manufacturers who provide raw materials and/or components used in the manufacture or assembly of a device.
- Manufacturers of devices used solely for veterinary purposes.
- Licensed practitioners, who manufacture/alter devices solely for use in their practice.
  - **may not distribute to other practitioners to keep exemption**
- Retail establishments that provide devices directly to end users.
  - **includes pharmacies, surgical supply outlets, etc.**
  - **note: shipments must be properly labeled**
- Manufacturers whose devices are used solely in research, teaching, or analysis and not introduced into commercial distribution.

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# When to Register & List

## Initial/First-Time Registration

- **Domestic establishments**
    - **within 30 days** of putting a device into commercial distribution
  - **Foreign establishments\***
    - prior to exporting to the United States for the first time
  - **Initial Importers\***
    - prior to importing to the United States for the first time
    - only register; do no list
    - must identify the manufacturer of each device imported
- \* Failure to do so may result in shipment detention by Customs/Border Patrol

# When to Register & List

## Annual Registration and Listing Certification

- **Establishments must certify that their registration information is complete and accurate**
  - must be done annually
  - between October 1 through December 31 of each year
  - make any changes as necessary
- **Information may be updated at any time**
  - strongly recommended if plan to discontinue, resume or begin marketing/distributing of a device

# Steps of Registration

## For all Establishments (Domestic/Foreign)

1. Pay the annual registration user fee.
2. Register the establishment in the FDA Unified Registration and Listing Systems (FURLS)
3. Provide information about the establishment, Owner Operator and Official Correspondent (name, address, phone, email, etc.)

# Steps of Registration

## For all Establishments (Domestic/Foreign)

4. Create at least one listing at time of initial registration
  - not required for initial importers
  - for devices that require a premarket submission, may not do this step until device is legally marketed
  
5. Identify all proprietary names under which the product is marketed in the United States



# Steps of Registration

## For Foreign Establishments only

7. Identify all persons you know of who import or who offer to import your product into the United States
8. Identify a United States agent

## For Initial Importers only

7. Identify manufacturers of the product you import by establishment name, address, establishment registration number or device listing number

# Foreign Establishment Liaison: United States (US) Agents

## Roles of the U.S. Agent

- assist the foreign establishment to communicate with FDA
- may be granted authority by foreign establishment to act as official correspondent
- receive official FDA information or documents
- respond to questions concerning products being imported or offered for import

## Restrictions

- must reside or have a place of business in the United States; no Post Office (P.O.) Box
- has no responsibility to report adverse events or submit 510(k)s

# Device Listing

- All establishments who must register also must list their devices
  - **Exception: initial importers/distributors do not list**
- Foreign establishments must list device before it can be imported into the United States
- Manufacturer or Specification Developer must list device first; then contract manufacturer or sterilizer may list
- For combination products, identify the type of combination
  - **e.g., device-biologic; device-drug, etc.**

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# Information You Need to Provide to List

- **For exempt/pre-Amendments devices**
  - product code for the device
  - activities performed at the establishment for the device (e.g., manufacture, relabel, etc.)
  - proprietary or brand names under which device is marketed
    - **may be marked confidential**

# Information You Need to Provide to List

- **For devices that require FDA premarket submission**
  - submission number from your clearance/approval letter (e.g., K123456, P123456)
  - activities performed at establishment for the device (manufacture, relabel, etc.)
  - proprietary or brand names under which device is marketed

# More Information about Listing

- Each successfully-created listing generates a unique listing number
- All of the establishments under an owner operator share the same listing number
- You can't enter a new listing:
  - for multiple exempt devices that use the same product code; and
  - non-exempt devices already listed by your company under a prior listing

# FURLS Registration and Listing

- **FDA's Unified Registration and Listing System (FURLS)**
  - **Device Registration and Listing Module (DRLM)**
  - web-based system
  - all establishments must use electronic, on-line system
    - unless **waiver** of electronic entry is granted



# Electronic Registration: **Waiver**

- submit written request to: Food and Drug Administration  
CDRH - Office of Compliance  
Registration & Listing  
10903 New Hampshire Avenue  
Building 66 Room 2621  
Silver Spring, MD 20993-0002
- explain why you are unable to electronically register and submit information through internet
- if approved, FDA will notify you
- if granted waiver, you are still responsible to pay establishment registration fee

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# FURLS Accounts

- **Two types of FURLS accounts**
  - **Owner Operator**
  - **Official Correspondent**
- **FURLS account is not the User Fee account**

# FURLS Accounts: Passwords

- must be reset every 90 days
- FURLS system will notify you to change password
- **don't forget current password!**
  - need this to reset password
- if you forget your password, try the reset password function first

**Note: Do not create a new FURLS account if the establishment was registered with FDA in the past, unless directed by FDA**

# FURLS Accounts

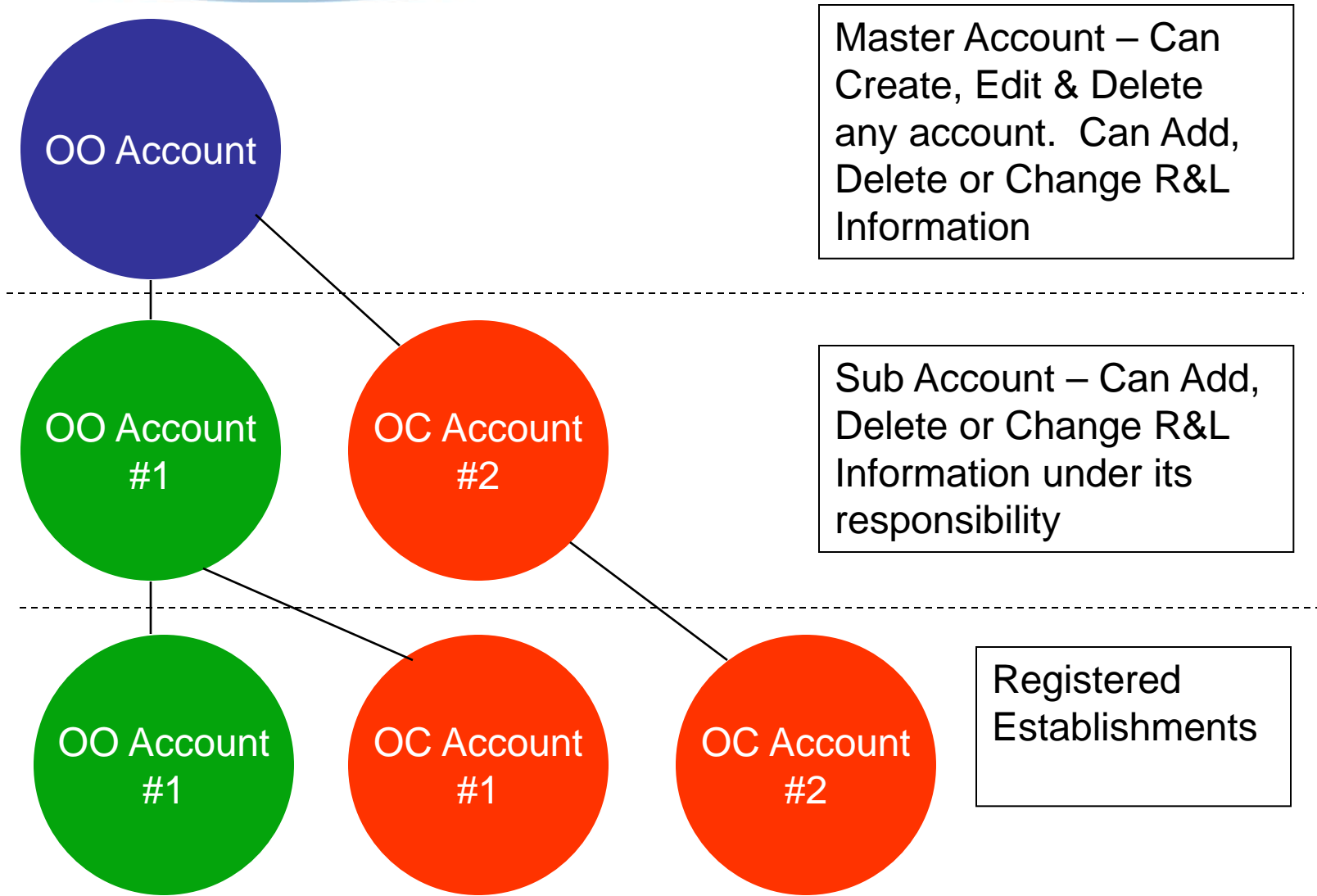
## Owner Operator Account (OO)

- referred to as “master,” “enterprise” or “primary account”
- assigned to the corporation, subsidiary, affiliated company, partnership, or proprietor directly responsible for the activities of the registered establishment
- creates and updates all FURLS accounts
- creates, updates and deactivates registrations and listings

# FURLS Accounts

## Official Correspondent

- assigned by the owner operator
- responsible for annual registration and device listing
- create new registrations and listings
- makes changes, updates and cancelations to registrations and listings that have been assigned to them
- cannot change the owner operator or official correspondent information (name, address, telephone, email etc.)



Master Account – Can Create, Edit & Delete any account. Can Add, Delete or Change R&L Information

Sub Account – Can Add, Delete or Change R&L Information under its responsibility

Registered Establishments

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# User Fees

- All Establishments required to register must first pay the Establishment Registration Fee
- Pay the fee by accessing your user fee account on the Device Facility User Fee website (DFUF)

Note this is a different account than what you use to complete your electronic R& L and must be completed first.

# What Information is Provided?

1. After you pay the annual registration user fee, you will receive via email:
  - **Payment Identification Number (PIN) and**
  - **Payment Confirmation Number (PCN)**
  
2. You will need your PIN and PCN to complete your FURLS registration.
  
3. Register establishment after you receive your PCN
  - **do not attempt to register without PCN**
  - **without PCN, you will have to re-enter all of your information**

## Annual Registration User Fees

Congress has established a schedule of annual registration user fees for each fiscal year as shown below

<b>Year</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
<b>Fee</b>	\$2,575	\$3,313	\$3,646	\$3,872*	\$3,872*

\* These fees are estimates based on projections. Actual fee for that fiscal year will be determined and posted by August prior to that fiscal year.

# Payment Methods

- Electronic Payments (such as credit cards or ACH electronic checks)
- Mailing in a paper check drawn on a U.S. bank in U.S. currency
- Wire Transfers

# Web Resources

- **Registration and Listing:**

<http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/registrationandlisting/default.htm>

- **Who Must Register, List and Pay Fee**

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm>

# Registration & Listing Email Contacts

- **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)