Device Registration and Listing: An Introduction – Part 2

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Device Registration and Listing Introduction

- **Part 1:**
  - **What, Why, and Who** is involved with registration and listing
- **Part 2:**
  - **How** to register and list

Learning Objectives

- List the steps to register
- Identify information needed to list
- Discuss how to use FURLS and DRLM
- Explain how user fees are paid

Steps to Register

Registration and Listing Steps: Domestic and Foreign Establishments

1. **Pay annual registration user fee**
   - Can't start establishment registration process before FDA has received and processed the fee
2. **Register establishment in FURLS**
   - Select DRLM and register establishment

FURLS = FDA Unified Registration and Listing System
DRLM = Device Registration and Listing Module

Registration and Listing Steps: Domestic and Foreign Establishments

3. **Provide necessary information**
   - Establishment, owner operator, and official correspondent
   - Name, address, phone, fax number and email
   - Establishment website address, if any
   - Trade names used by establishment

Registration and Listing Steps: Domestic and Foreign Establishments

4. **Create at least one device listing, at time of initial registration**
   - Device must be legally marketed before listing such as:
     - Exempt
     - Premarket Notification [510(k)]: Substantially equivalent or “cleared”
     - Premarket Approval [PMA] or Humanitarian Device Exemption: Approved
     - De Novo Classification Request: Granted

   ➢ **Note: Excludes initial importers**

Registration and Listing Steps: Domestic and Foreign Establishments

5. **Identify all proprietary names**
   - Under which device is marketed in United States
   - May mark as “confidential” so name will not publicly display in public registration and listing database

Registration and Listing Steps:
Additional for Foreign Establishments Only

6. **Identify all persons you know who import (or offers for import) your product into United States**
7. **Identify a U.S. Agent**
   - Agent must confirm that they are the U.S. Agent for the foreign establishment
   - If not completed, FDA may designate as “failed to register”

Registration and Listing Steps:
Additional for Initial Importers Only

6. Identify manufacturer of device you import

- Either device listing, if you know; OR
- Manufacturer's name
  - Manufacturer should already have registered in FURLS and identified importer during registration

→ FDA does not provide device listing information to importers

United States Agent

- Assists FDA to communicate with Foreign Establishment
- Granted authority by Foreign Establishment to act as their official correspondent
- Receives official FDA information or documents
- Responds to questions about imported devices

United States Agent

- Must reside or have place of business in United States
  - Cannot use Post Office (P.O.) Box for address
- Has no responsibility to report adverse events
- Has no responsibility to submit marketing submissions

➢ **Note to Foreign Establishment**:

- Update changes to your U.S. Agent in FURLS/DRLM within 10 business days

Listing Your Medical Device

Information Needed to List Device

- **Establishment registration number and name**
- **Activities performed at establishment**
  - Examples: manufacturing, labeling
- **Regulatory Information:**
  - **Product Code:** if your device is exempt from premarket submission or in distribution prior to May 28, 1976 (“Pre-Amendments”)
  - **Premarket submission number:** if not exempt or Pre-Amendments
    - Examples: K239999; P239999; DEN239999; H239999

Device Listing: Additional Details

- Each successfully-created listing generates a unique listing number
- All establishments under owner or operator may share same listing number
- Cannot create a new device listing for:
  - Multiple exempt devices with same product code
    - Except for manufacturers of export only
  - Multiple non-exempt devices with same premarket number, under same registration

Device Listing: Additional Details

- All establishments who must register must also list their devices
  - Exception: Initial Importers are not required to list
- Foreign establishments
  - Must list device before it may be imported into United States
- Device List Sequence
  - First: manufacturer or specification developer
  - Second: Contractor manufacturer or contract sterilizer
- Combination products – identity “type” of combination
  - Examples: “Device-Biologic”, “Device-Drug”

Using FURLS and DRLM

FURLS and DRLM

- **FDA Unified Registration and Listing System (FURLS)**
  - Web-based, online system to electronically submit information
  - From here, select **Device Registration and Listing Module** (DRLM)

www.access.fda.gov/oaa/logonFlow.htm?execution=e2s1

Waiver of Electronic Submission

- Submit request to CDRH FURLS Team:
  - Email to: Device.Reg@fda.hhs.gov (preferred); or
  - Mail letter to:

    Imports and Registration and Listing Team
    Division of Regulatory Programs 2
    Office of Regulatory Programs
    Office of Product Evaluation and Quality
    Center for Devices and Radiological Health
    Food and Drug Administration
    10903 New Hampshire Avenue, Building 66, Room 1432
    Silver Spring, MD 20993

Waiver of Electronic Submission

- Explain why unable to electronically submit information

- FDA will notify if waiver is granted:
  - Note: You are still required to pay user fee

FURLS Account Types

- Owner/Operator
- Official Correspondent (OC)

➢ **Important Note:**

– **FURLS** account is different from a **User Fee** account

FURLS Account Password

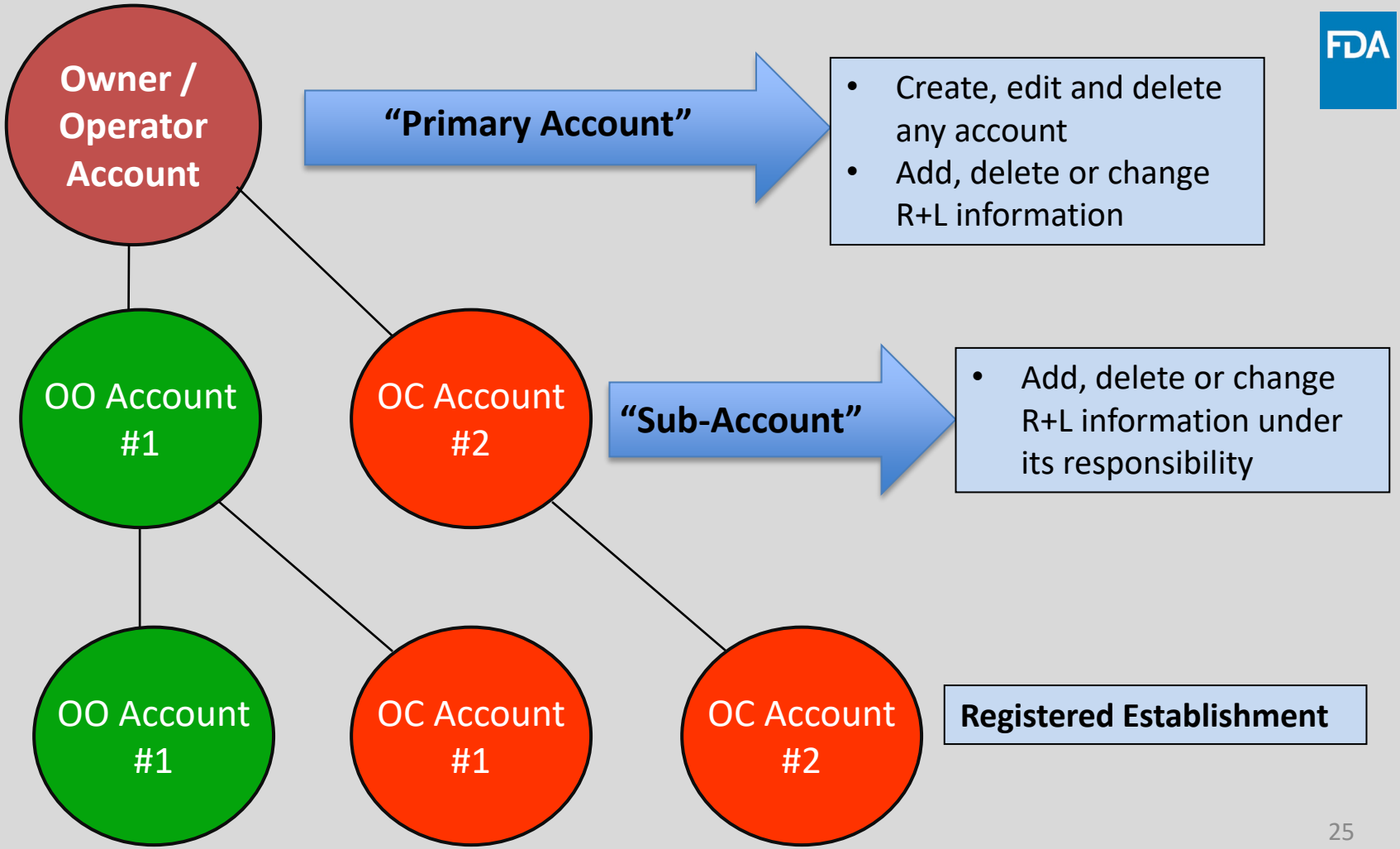
- **Must change every 90 days**
  - Need current (old) password to make change
- **If you forget password:**
  - First attempt to recover with “Forgot Password”
  - Need Account ID, Secret Question and Secret Answer
- **If “Forgot Password” doesn’t work and you need help:**
  - Contact CDRH R&L Help Desk (reglist@cdrh.fda.gov)
  - Do not create new FURLS account; FDA will guide you

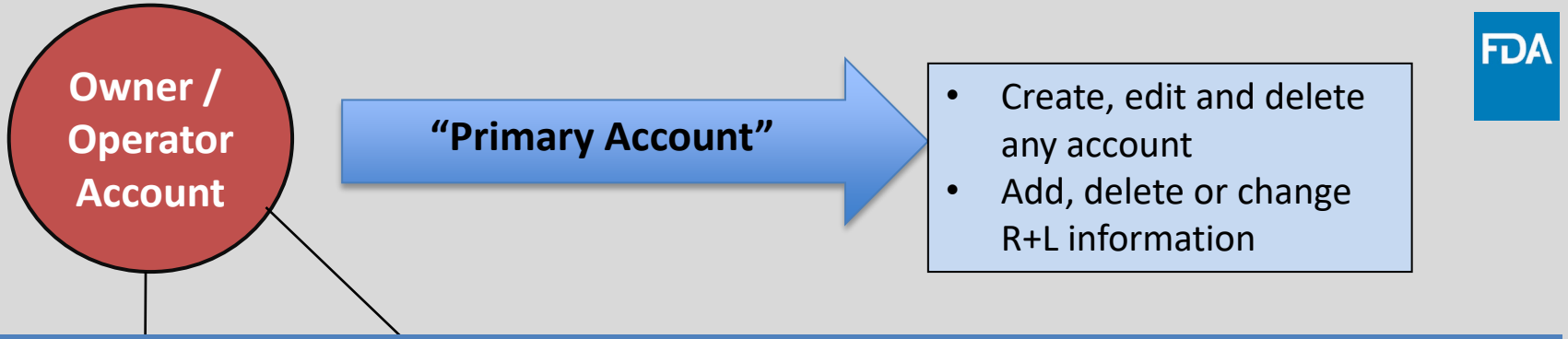
Owner/Operator Account

- “Enterprise” or “Primary Account”
- Corporation or proprietor directly responsible for activities of registered establishment
- Creates and updates all FURLS sub-accounts, official correspondent accounts, registrations and listings
- Deactivates registrations and listings

Official Correspondent Account

- Assigned by owner/operator
- May complete registration and listing for any establishment under responsibility
- May create new, update, and cancel registration and listing assigned to them
- May not change owner/operator or official correspondent information


Owner / Operator Account
"Primary Account"
• Create, edit and delete any account
• Add, delete or change R+L information
OO Account #1
OC Account #2
"Sub-Account"
• Add, delete or change R+L information under its responsibility
OO Account #1
OC Account #1
OC Account #2
Registered Establishment



To find out what type of account you have:

1. Log into FURLS
2. Go to Account Management Menu
3. Look for "Edit Account Profile"
4. If you see "Edit Account" profile button, then you are signed in as Owner/Operator

User Fee for Establishment Registration

Establishment Registration User Fee

- All establishments required to register must pay establishment registration user fee
- To pay fee:
  - Set up/access your user fee account on Device Facility User Fee (DFUF) website

➢ **Important Note:** Your FURLS and DFUF Accounts are not the same; they have different ID and passwords

DFUF Website: userfees.fda.gov/OA_HTML/furls.jsp

Paying User Fee Then Register

1. **After you pay annual registration user fee, FDA will email you:**
   - Payment Identification Number (PIN) and
   - Payment Confirmation Number (PCN)

2. **After you receive your PCN, register establishment in FURLS:**
   - Need to use both PIN and PCN to complete

Establishment Registration User Fee: Amount

- Congress establishes the user fee amount
- Set for each fiscal year
  - From October 1 of current year through September 30 of next year

- Current Fiscal Year User Fee:

www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing

Establishment Registration User Fee: Payment Methods

- **Electronic payment**
  - Examples: Credit cards or automated clearing house electronic checks
- **Mailed paper check**
  - Drawn on a United States Bank in U.S. currency
  - Make payable to “Food and Drug Administration”
  - Include the PIN
- **Wire transfer**
  - Establishments are responsible for paying all wire transfer fees

For Questions

- **Registration and Listing Process or FURLS/DRLM**
  - RegList@cdrh.fda.gov

- **Policy or Import Detention Issues**
  - Device.Reg@fda.hhs.gov

Registration and Listing Process or FURLS/DRLM

Policy or Import Detention Issues

Resources

Slide Number	Cited Resource	URL
18	FURLS	www.access.fda.gov/oaa/logonFlow.htm?execution=e1s1
26	DFUF	userfees.fda.gov/OA_HTML/furls.jsp
28	Device Advice: Device Registration and Listing	www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing

FURLS

DFUF

Device Advice: Device Registration and Listing

Other Related CDRH Learn Modules

- **FURLS Device Registration and Listing Module for Initial Registration**

  www.accessdata.fda.gov/cdrh_docs/presentations/FURLS/story.html

- **FURLS Device Registration and Listing Module for Annual Registration**

  www.fda.gov/media/107672/download

FURLS Device Registration and Listing Module for Initial Registration

Scan Me

FURLS Device Registration and Listing Module for Annual Registration

Scan Me

Summary

- An establishment follows a series of steps to complete establishment registration
- Specific information is needed to list devices
- FURLS is the online electronic system used to complete this process
- FURLS Account types include Owner/Operator, Official Correspondent
- Establishments use the DFUF user fee system to pay the required annual registration user fee and then complete registration

Industry Education

1. **CDRH Learn – Multi-Media Industry Education**
   - over 200 modules - videos, webinars, presentations, software-based “how to” modules
   - accessible on your portable devices: **www.fda.gov/CDRHLearn**

2. **Device Advice – Text-Based Education**
   - comprehensive regulatory information across the device total product life cycle: **www.fda.gov/DeviceAdvice**

3. **Division of Industry and Consumer Education (DICE)**
   - Email: **DICE@fda.hhs.gov**
   - Phone: 1-800-638-2041 or (301) 796-7100 (Live Agents 9 am – 12:30 pm; 1 – 4: 30 pm ET)

CDRH Learn

Device Advice

Email DICE

Your Call To Action

- Learn the steps to successfully register your establishment and list your devices
- Pay your user fee before you of register and list
- Use the FDA educational resources to help you complete the initial and annual registration process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