Medical Device Establishment Registration & Listing

FDA Small Business
Regulatory Education for Industry (REdI)
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Presentation Outline

• Registration & Listing Regulatory Requirements
• Who Is Required To Register & List
• When To Register & List
• How To Register & List
• Registration & Listing References
• Discussion
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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

- **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 Continued

• 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 Continued

21 CFR Part 807- Establishment Registration and Device Listing For Manufacturers and Initial Importers of Devices

Subpart A: General Provisions/Definitions
Subpart B: Procedures for Device Establishments
Subpart C: Procedures for Foreign Device Establishments
Subpart D: Exemptions
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Who Is Required to Register

**Domestic Establishments**

- Manufacturers, Including Kit Assemblers
- Remanufacturers
- Repackagers/Relabelers
- Contract Manufacturers/Sterilizers
- Specification Developers
- Reprocessors of Single Use Devices
- Complaint Handlers
- Initial Importers (Initial Distributors)

*Note: Domestic Distributors are not required to register & list.*
Who Is Required to Register

Foreign

- Manufacturers, Including Kit Assemblers
- Remanufacturers
- Repackagers/Relabelers
- Contract Manufacturers/Sterilizers
- Specification Developers
- Reprocessors of Single Use Devices
- Complaint Handlers
- Private Label Distributors
- Foreign Exporters

*Note: Foreign establishments are only required to register if their devices are imported into the U.S.*
Exemptions from Registration & Listing 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.

- 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.
Summary Table: Who Must Register, List and Pay the Fee

Reference:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm
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When to Register & List 
(Initial/First-Time Registration)

• **Domestic Establishments:**
  – Within **30 days** of beginning manufacturing.

• **Foreign Establishments:**
  – Prior to exporting a regulated medical device to the United States for the first time.
  – *Note: Failure to register may result in shipment detention by Customs/Border Patrol.*

• **Initial Importers:**
  – Prior to importing a regulated medical device into the United States for the first time.
  – Only required to register; they do no list products
  – Must identify the foreign manufacturer of each device imported.
  – *Note: Failure to register may result in shipment detention by Customs/Border Patrol.*
When to Register & List
(Annual Registration & Listing Certification)

• Establishments must certify **annually** that their registration information is complete and accurate.
  – Certify between October 1 and December 31 of each year.
  – Must make any changes as necessary (e.g. proprietary names, etc.).

• Registration and Listing information may be updated at any time.
  – Example, FDA strongly recommends if an establishment plans to discontinue marketing and distributing of a device, that they deactivate the listing for the device.
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## How to Register & List: Overview of the Necessary Steps

<table>
<thead>
<tr>
<th>Domestic Establishments</th>
<th>Foreign Establishments</th>
<th>Initial Importers</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Pay the annual User Fee via the Device Facility User Fee (DFUF) website.</td>
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<td>3. List your device(s) in FURLS and identify all proprietary names. *Note: May mark names as confidential.</td>
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<td>4. Identify Manufacturer for each product imported *Note: Initial Importers do not list the devices they import.</td>
</tr>
<tr>
<td>5. Identify U.S. Agent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Identify all importers known to the establishment</td>
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<td></td>
</tr>
</tbody>
</table>
Step 1: Pay Annual User Fee in DFUF

• All Establishments required to register must first pay the Establishment Registration User Fee.

• The user fee is paid by accessing your user fee account via the DFUF website (https://userfees.fda.gov/OA_HTML/furls.jsp).

*Note: Your DFUF account is different than your FURLS Registration & Listing account.

• 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
Step 1 Continued: Annual Registration User Fees

<table>
<thead>
<tr>
<th>Year</th>
<th>FY 2013</th>
<th>FY 2014</th>
<th>FY 2015</th>
<th>FY 2016</th>
<th>FY 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>User Fee</td>
<td>$2,575</td>
<td>$3,313</td>
<td>$3,750</td>
<td>$3,872</td>
<td>$3,872</td>
</tr>
</tbody>
</table>

*Schedule of annual registration user fees, as established by Congress. Subject to change.*
Step 1 Continued: User Fee Reminders

✓ After you pay the annual registration user fee, you will receive via email:
  ✓ Payment Identification Number (PIN) and
  ✓ Payment Confirmation Number (PCN)

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

✓ Register your establishment only after you receive your PCN.
Step 2: Register Your Establishment in FURLS

- On-line system: Device Registration and Listing Module (DRLM) within FURLS
  https://www.access.fda.gov/oaa/logonFlow.htm?execution=e2s1

- Establishments use the electronic, on-line system to register

- You will provide information about your establishment, Owner Operator and Official Correspondent (name, address, phone, email, etc.).
Step 2 Continued: FURLS Passwords

• Passwords must be reset every 90 days.
• FURLS system will notify you when to reset password. Reminder: You will need your current password to reset.
• If you forget your password, try the reset password function first in FURLS. If unsuccessful, contact Registration and Listing Office.
• *Note: Do not create a new FURLS account if the establishment was registered with FDA in the past, unless directed by FDA.

*Reminder: Your FURLS account is not your User Fee account.
Step 2 Continued: FURLS Accounts

<table>
<thead>
<tr>
<th>Owner Operator Account (OO)</th>
<th>Official Correspondent (OC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Referred to as “master” or “primary account.”</td>
<td>• Assigned by the owner operator.</td>
</tr>
<tr>
<td>• Assigned to the corporation, subsidiary, affiliated company, partnership, or proprietor directly responsible for the activities of the registered establishment.</td>
<td>• Responsible for annual registration and device listing.</td>
</tr>
<tr>
<td>• Creates and updates all FURLS accounts.</td>
<td>• Create new registrations and listings.</td>
</tr>
<tr>
<td>• Creates, updates and deactivates registrations and listings.</td>
<td>• Makes changes, updates and cancelations to registrations and listings that have been assigned to them.</td>
</tr>
<tr>
<td></td>
<td>• Cannot change the owner operator or official correspondent information (name, address, telephone, email etc.).</td>
</tr>
</tbody>
</table>
Step 3: List Your Device(s) in FURLS and Identify All Proprietary Names

Information Required to List:

- If applicable, submission number(s) from your clearance/approval letter(s) (e.g., K123456, P123456).
  *Note: You cannot complete your registration and listing until you receive the appropriate premarket clearance or approval.

- Product code for devices exempt from premarket approval or clearance

- Activities performed at the establishment for each device (e.g. manufacture, relabel, etc.).

- Proprietary or brand name(s) under which device is marketed in the U.S.
  *Note: May be marked as confidential in FURLS.
Step 3 Continued: Device Listing Reminders

- All establishments who must register must also list their devices, except initial importers.
- FDA uses listing information to identify types of devices that an establishment provides to the U.S. market or imports to the U.S.
- Listing information is public, except device listing numbers and proprietary names(s) if they were marked as confidential.
- Manufacturers and specification developers must list their device(s) first; then contract manufacturers or sterilizers may list.
- For combination products, you must identify the type of combination (e.g., device-biologic; device-drug, etc.).
- Each successfully created listing generates a unique device listing number.
- You cannot enter a new listing for multiple exempt devices that use the same product code.
Step 4: For Initial Importers Only

• Must identify foreign manufacturer(s) of the products they import. May be identified by listing number, registration number or name and/or address of manufacturer.

• Important notes for initial importers:
  – Initial importers do not list the devices they import.
  – As an initial importer you cannot complete your registration until your foreign supplier has completed their registration and listing.
Step 5: For Foreign Establishments Only

• Must identify only one U.S. Agent.
• Foreign establishment must provide the name, address, telephone and e-mail address of the U.S. Agent.
• Responsibilities of a U.S. Agent:
  – Assist the FDA in communications with foreign establishment.
  – Respond to questions concerning products being imported or offered for import into U.S.
  – Able to receive official FDA information and/or documents, if FDA unable to contact foreign establishment.
  – No responsibility to report adverse events or submit premarket notifications [510(k)s].
• U.S. Agent Requirements:
  – The U.S. Agent must either reside in the U.S. or maintain a place of business in the U.S.
  – The U.S. agent cannot use a post office box as an address.
• Identify the person(s) you know who import(s) or who offer(s) to import your product(s) into the U.S.

Steps 6 Continued: For Foreign Establishments Only
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General Industry Resources

• **CDRH Learn**
  – Modules include various premarket and post-market information including a updated module of Registration and Listing
  – Available 24/7
  – Certificate generated per topic upon passing post-tests, if available

• **Division of Small Manufacturers, International, and Consumer Assistance (DSMICA)**
  – Phone: 1-800-638-2041 or 301-796-7100
  – Email: dsmica@fda.hhs.gov
Web Resource: How to Register & List

(Reference: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053185.htm)
Registration & Listing Resources

• Registration & Listing status or process questions:
  – Phone: 301-796-7400, Option 1
  – Email: reglist@cdrh.fda.gov

• Assistance with policy questions and import detention issues:
  – Phone: 301-796-7400, Option 2
  – Email: device.reg@fda.hhs.gov

• FURLS/DRLM technical questions: 1-800-216-7331

• User Fee or DFUF questions:
  – Phones: 301-796-7200
  – Email: userfees@fda.gov
Registration & Listing Reference: Online Feedback Form

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