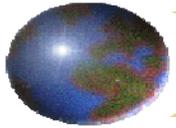


U.S. Food and Drug Administration
Device Establishment Registration and Listing

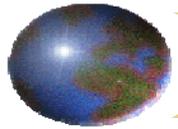
*Presenter: Nicole Taylor Smith, Assistant Country Director
China Office, U.S. Food and Drug Administration*

*ITA-FDA Medical Devices Regulatory Capacity Building Training Program for International Medical Devices Regulators
March 27 - 28, 2014; San Francisco, California*



Overview

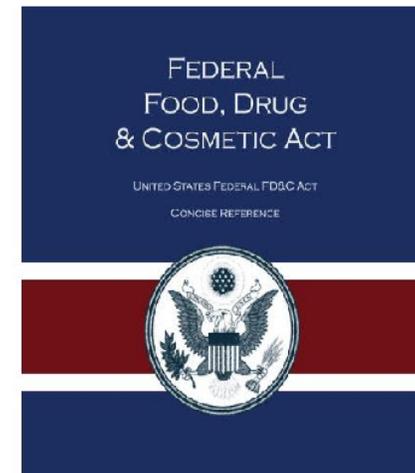
- Regulatory Requirements for Device Establishment Registration and Listing
- Why? Purpose of Registration and Listing
- Who? Who Must Register and List
- When? When to Register and List
- What? What are the Requirements
- United States Agent
- How? How to Register and List
- Fees
- Resources and Contacts



Regulatory Requirements

- **Section 510 of the Food, Drug, and Cosmetic Act (21 U.S.C. § 360)**

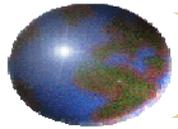
- Enacted in **1976** (since amended)
- Required medical device establishments to annually register and list with FDA
- Misbranded if devices manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered or listed



- **Food and Drug Administration Amendments Act (FDAAA)**

- Enacted in September **2007**
- Mandated electronic registration and listing
- Required user fees for many establishments

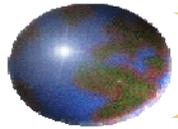
*ITA-FDA Medical Devices Regulatory Capacity Building Training Program for International Medical Devices Regulators
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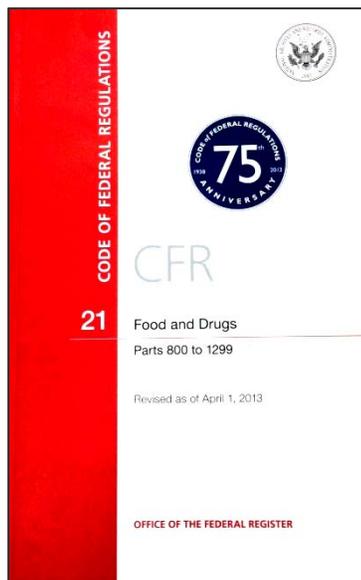
Regulatory Requirements

- Food and Drug Administration Safety and Innovation Act (FDASIA)
 - Enacted July **2012**
 - Expanded user fee requirements to all establishment types

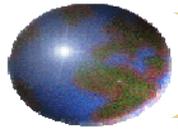
- 21 Code of Federal Regulations (CFR) Part 807, revised
 - Published August 2, **2012**
 - Regulations promulgated to implement law



Regulatory Requirements



- 21 CFR 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

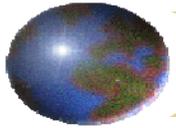


Regulatory Requirements

Failure to Register and List

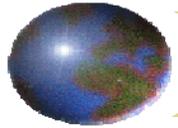
- Section 502(o) of the Food, Drug, and Cosmetic Act (21 U.S.C. § 352(0))

Devices are considered **misbranded** if manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 of the Act, 21 U.S.C. § 360, and are not included in a list required by section 510(j) of the Act, 21 U.S.C. § 360(j) (emphasis added).



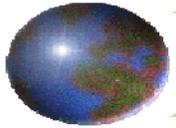
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- Resources and Contacts



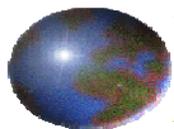
Why? Purpose of Registration and Listing

- Establishment registration and listing provides FDA with the **location** of medical device establishments and a **list of devices** manufactured at those establishments.
- Knowing where devices are made increases the ability to prepare for and respond to **public health emergencies**.



Overview

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Who? Who Must Register and List

● Domestic

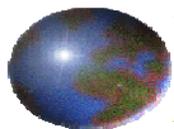
- Manufacturers/Remanufacturers
 - Kit Assemblers
- Repackagers/Relabelers
- Contract Manufacturers/Sterilizers
- Specification Developers
- Reprocessors of Single Use Devices
- Complaint Handlers
- Initial Importers (Initial Distributors)

Note: domestic distributors need not register

● Foreign

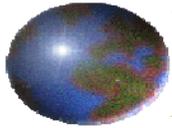
- Manufacturers/Remanufacturers
 - Kit Assemblers
- Repackagers/Relabelers
- Contract Manufacturers/Sterilizers
- Specification Developers
- Reprocessors of Single Use Devices
- Complaint Handlers
- Foreign Exporters and Private Label Distributors

Note: applies only if devices are sold in the United States



Who? Who Must Register and List

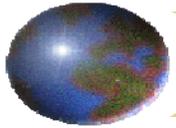
| Establishment Type | Domestic | Foreign |
|---|-----------------|----------------|
| Manufacturers/Remanufacturers/ Kit Assemblers | Yes | Yes |
| Specification Developer | Yes | Yes |
| Contract Manufacturer/Sterilizer | Yes | Yes |
| Repackagers/Relabelers | Yes | Yes |
| Reprocessors of Single Use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



Who? Who Must Register and List

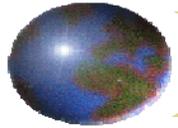
● Exemptions – Not Required to Register/List

- A manufacturer of raw materials or components to be used in the manufacture or assembly of a device
- A manufacturer of devices used solely for veterinary purposes
 - Regulated by FDA's Center for Veterinary Medicine
- Licensed practitioners who manufacture or otherwise alter devices solely for use in their practice
 - Exemption is void if distributed to other practitioners
- Retail establishments that provide devices directly to end users
 - For example, pharmacies, surgical supply outlets, etc.
 - Note: establishments receiving goods from foreign establishments should make sure their shipments are properly labeled
- Persons who manufacture, prepare, propagate, compound, or process devices solely for use in research, teaching, or analysis and do not introduce such devices into commercial distribution



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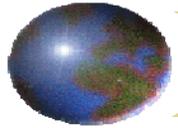


When? When to register and list

- 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

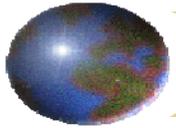
- Initial Importers
 - ▣ Prior to importing to the United States for the first time
 - ▣ Only need to register; do not need to list
 - ▣ Must identify the manufacturer of each device imported



When? When to register and list

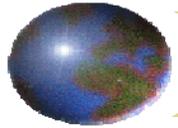
Annual Registration and Listing Certification

- Establishments must certify their registration information is complete and accurate
 - ❑ Annually
 - ❑ Between October 1 through December 31 of each year
 - ❑ Make changes as necessary
- Information may be updated at any time
 - ❑ Strongly recommend if plans change, i.e. plans to discontinue, resume or begin marketing/distributing a device



Overview

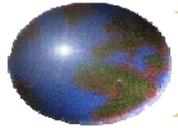
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What? What are the Requirements - Registration

All establishments (domestic/foreign) must:

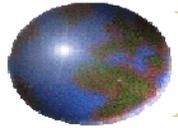
1. Pay the annual registration fee
2. Register the establishment in the FDA Unified Registration and Listing Systems (FURLS)
3. Provide information about the establishment, Owner Operator and Official Correspondent (name, address, phone, email, etc.)



What? What are the Requirements - Registration

All establishments (domestic/foreign) must:

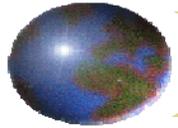
4. Create at least one listing at time of initial registration
5. Identify all proprietary names under which the product is marketed in the United States



What? What are the Requirements - Registration

Foreign Establishments must:

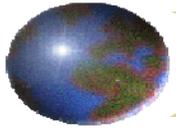
1. Identify all persons you know of who import or who offer to import your product into the United States
2. Identify a United States Agent



What? What are the Requirements - Registration

Initial Importers must:

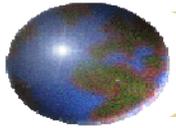
1. Identify manufactures of the product you import by establishment name, address, establishment registration number or device listing number



What? What are the Requirements – Listing

Device Listing

- Most establishments that are required to register with FDA are also required to list devices made at the establishment and the activities performed on the devices (Exception: Initial Importers/Distributors are not required to 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 the combination (i.e., drug/device, etc.)



What? What are the Requirements – Listing

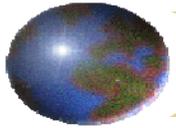
● Information needed to list

■ For exempt/pre-amendment devices:

- Product code
- Activities performed at establishments for the device (i.e., manufacturing, relabel, etc.)
- Proprietary or Brand name of the marketed device (this information may be marked confidential)

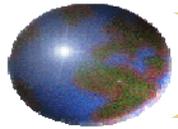
■ For devices that required FDA premarket submission:

- Submission number from your clearance/approval letter (KXXXXXX; or PXXXXXX)
- Activities performed at establishment for the device (i.e., manufacturing, relabel, etc.)
- Proprietary or Brand name of the marketed device (this information may be marked confidential)



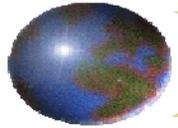
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United States Agent

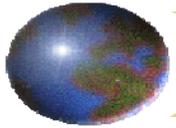
- All Foreign Establishments must have a United States Agent
- Roles of Agent:
 - Assist in communication with FDA
 - May be granted authority by foreign establishment to act as official correspondent
 - Receive official FDA information or documents
 - Respond to questions concerning products being imported or offered for import



United States Agent

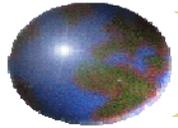
● Responsibilities

- Information about a foreign establishment's U.S. agent is submitted electronically using the FURLS system and is part of the establishment registration process
- Each foreign establishment may designate only one U.S. agent
- Agent must reside or have a place of business in the United States with someone to answer the phone during normal business hours; Post Office Box (P.O. Box) is not sufficient; and cannot just have an answering service
- Agent does not have responsibility to report adverse events or submit 510(k)s



Overview

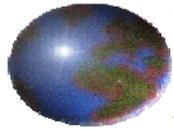
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How? How to Register and List

How to register and list

- For all establishments (domestic/foreign) you must register electronically using FDA's web-based Registration and Listing System (FURLS) (unless waiver is granted by FDA)



How? How to Register and List

FURLS

- ❑ Two types of accounts:
 - Owner Operator;
 - Official Correspondent
- ❑ Passwords: must be reset every 90 days
- ❑ Note: do not create a new FURLS account if the establishment was registered with FDA in the past, unless directed by FDA

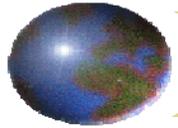
FDA Industry Systems / FDA Unified Registration and Listing Systems (FURLS)

FDA Industry Systems [SYSTEM STATUS](#) [HELP DESK](#)

LOGIN
Existing account holders, enter your account ID & password.
Account ID:
Password:
 I Understand
LOGIN [Forgot your password?](#)

GETTING STARTED
To make submissions to FDA (e.g., Food Facility Registration, Prior Notice, etc.) you must first create an account. Select "Create New Account" below.
If you already have an account, enter your account ID and password.
WARNING: You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording, and Anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.
Is your computer secure? Before using FDA Industry Systems (FIS), FDA strongly encourages a users to have current antivirus and antispayware software installed on your computer to help ensu the privacy of the information being entered.
FDA retains contractors to assist the agency in maintaining its databases. If you get a call from someone asking about your facility and you are concerned about whether the call is legitimate, g the name and company of the caller, as well as a phone number, and contact [FDA FURLS](#)

<https://www.access.fda.gov/oaa/logonFlow.htm?execution=e3s1>



How? How to Register and List

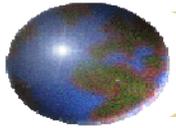
● FURLS

■ Owner Operator Account

- “Master,” “Enterprise,” or “Primary Account”
- Assigned to corporation, subsidiary, etc.
- Creates and updates all FURLS accounts
- Creates, updates and deactivates registrations and listings

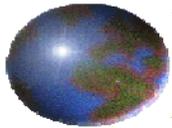
■ Official Correspondent Account

- Assigned by Owner Operator
- Responsible for annual registration and device listing
- Creates new registration and listings
- Makes changes, updates
- Cannot change the Owner Operator or Official Correspondent information (i.e., name, address, telephone, email, etc.)



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Fees



Useful Links

- [User Fee Information](#)
- [User Fee Payment Information](#)
- [Frequently Asked Questions \(FAQs\)](#)
- [FDA User Fee Account Creation: Step-by-Step Instructions](#)
- [FURLS Cover Sheet Creation: Step-by-Step Instructions](#)

System for Award Management

If you are a domestic entity and are requesting a refund, we recommend that you create an account with the System for Award Management (SAM). SAM validates the registrant information and electronically shares the encrypted data securely with the FDA to facilitate your refund. Click [here](#) to access SAM.

https://userfees.fda.gov/OA_HTML/furls.jsp

Log in to the User Fee System

User Name: Password:

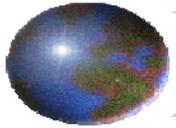
[Forgot User Name/Password?](#)

[New User? Please create a User Fee account.](#)

User Fee System Alerts

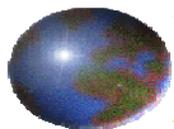
Please note that the FURLS/DRUM account ID and password (used for registering your facility) is separate from the user name and password for the User Fee website (used for the Device Facility User Fee (DFUF) payment). If you have questions regarding the registration process, please contact the CDRH Registration and Listing Helpdesk at realisti@cdrh.fda.gov or 301-796-7400.

- **All** Establishments required to register must first pay the annual Establishment Registration Fee
- Pay fee by accessing your user fee account on the Device Facility User Fee Website (DFUF) (not FURLS)
- Must complete payment of user fees on DFUF first before completing electronic registration and listing on FURLS



Fees

- After you pay the annual registration user fee on DFUF, you will receive by e-mail:
 - PIN (Payment Identification Number)
 - PCN (Payment Confirmation Number)
- You will use your PIN and PCN to complete your FURLS registration



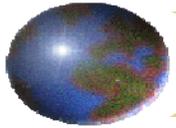
Fees

● Annual Registration User Fees

| Year | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|------|---------|---------|---------|---------|---------|
| Fee | \$2,575 | \$3,200 | \$3,750 | \$3,872 | \$3,872 |

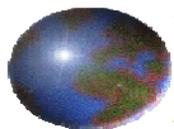
● Payment Methods

- ❑ Electronic Payments (i.e. credit card, ACH electronic checks)
- ❑ By mail – paper check drawn on U.S. bank check in U.S. currency
- ❑ Wire Transfers



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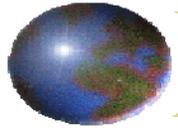
Resources and Contacts

The screenshot shows the FDA website header with the logo and navigation menu. Below the header is the title "Establishment Registration & Device Listing" with breadcrumb links for "FDA Home", "Medical Devices", and "Databases". A text box explains that the database includes medical device establishments registered with FDA and medical devices listed with FDA. A note states that registration or listing does not denote approval. Below this is a search form with fields for Establishment Name, Registration Number, Owner/Operator Name, Owner/Operator Number, Proprietary, and Classification. There are also links for "Help" and "Download Files".

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>

- Releasable establishment registration and listing information under the Freedom of Information Act is available by searching the **Establishment Registration and Listing database**
- This database includes:
 - medical device establishments registered with FDA, and
 - medical devices listed with FDA
- Updated weekly, usually every Monday

- Reminder: Registration of a device establishment, assignment of a registration number, or listing of a medical device does not in any way denote approval of the of the establishment or its products by FDA



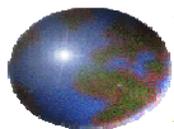
Resources and Contacts

● FDA's website:

- Registration and Listing:
www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm
- Who Must Register, List and Pay Fee:
www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm

● Contact Information:

- CDRH Registration and Listing Helpdesk (including FURLS/DRLM): at reglist@cdrh.fda.gov, 301-796-7400
- Assistance with policy questions and import detention issues: device.reg@fda.hhs.gov



Quick Recap

Annual Registration

- ✓ Registration information must be submitted each year between October 1 and December 31, even if no changes have occurred.
- ✓ Listing information must be reviewed each year between October 1 and December 31, at the same time you review your registration information. Submit any updates at that time.

Initial Registration

- ✓ Submit registration and/or listing information within 30 days of an establishment beginning an activity or putting a device into commercial distribution; foreign establishments must register before exporting products to the United States, and domestic importers must register before importing products.
- ✓ Reminder that if your device requires premarket notification clearance or approval, you will have to wait until your premarket submission [510(k), PMA, etc.] is cleared or approved to register your establishment and list the device.

Update Registration & Listing Information

- ✓ Can access FURLS at any time throughout the year to update changes to registration and listing information
- ✓ Establishment registrations are based on FDA's fiscal year which runs from October 1 to September 30. However, FDA will continue to consider an establishment's registration active through the end of each calendar year.

Reminders:

- Complete of annual establishment registration fee on Device Facility User Fee Website (DFUF) first before completing electronic registration and listing on FURLS
- Additional information is available at: www.fda.gov



Questions??

