



# Establishment Registration and Device Listing

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# Learning Objectives

- Statutory Basis for Registration and Listing
- Relevant Regulations
- Who Must Register and List
- When to Register and List
- How to Register and List
- Avoiding Common Mistakes



# Establishment Registration: Overview

- FDA authority to require registration of medical device establishments derived from **Federal Food, Drug, & Cosmetic Act** (21 U.S.C. § 360(c))
- FDA regulations promulgated at 21 C.F.R. Part 807

## **(c) New producers**

Every person upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices in any establishment which he owns or operates in any State shall immediately register with the Secretary his name, place of business, and such establishment.

# Establishment Registration: Who Must Register

21 C.F.R. § 807.20:

- Unless exempt, an owner or operator of an establishment who is engaged in the **manufacture, preparation, propagation, compounding, assembly, or processing** of a device intended for human use
- Registration information may be submitted by the parent, subsidiary, or affiliate company for establishments under their control when there exists joint ownership and control among all the establishments

# Establishment Registration: Who Must Register

21 C.F.R. § 807.40:

- Any establishment within any foreign country engaged in the **manufacture, preparation, propagation, compounding, or processing** of a device that is imported or offered for import into the United States
- Each foreign establishment must submit the name, address, and phone number of its United States agent as part of its registration information
  - Each foreign establishment may designate only one U.S. agent
  - The U.S. agent must reside or maintain a place of business in the U.S.

# Establishment Registration: Who Must Register

Establishment Type	Applicable Regulation(s)
Contract manufacturer (including contract packager)	21 C.F.R. § 807.20(a)(2) 21 C.F.R. § 807.40(a)
Contract sterilizer	21 C.F.R. § 807.20(a)(2) 21 C.F.R. § 807.40(a)
Custom device manufacturer	21 C.F.R. § 807.20(a)(2)
Establishment located in a foreign trade zone (if otherwise falls into one of these categories)	
Foreign exporter of devices located in a foreign country	21 C.F.R. § 807.40(a)

# Establishment Registration: Who Must Register

Establishment Type	Applicable Regulation
Foreign manufacturers (including kit assemblers)	21 C.F.R. § 807.40(a)
Initial importer	21 C.F.R. § 807.40(a)
Maintains complaint files as required under 21 C.F.R. § 820.198	
Manufacturer of accessories or components packaged/ labeled for commercial distribution to an end user	21 C.F.R. § 807.20(a)(6)
Manufacturer (including kit assemblers)	21 C.F.R. § 807.20(a)

# Establishment Registration: Who Must Register

Establishment Type	Applicable Regulation
Manufacturer of a custom device	21 C.F.R. § 807.20(a)(2)
Relabeler or Repackager	21 C.F.R. § 807.20(a)(3)
Remanufacturer	
Reprocessor of single use devices	21 C.F.R. § 807.20
Specification developer	21 C.F.R. § 807.20(a)(1)
U.S. manufacturer of export only devices	21 C.F.R. § 807.20(a)(2)

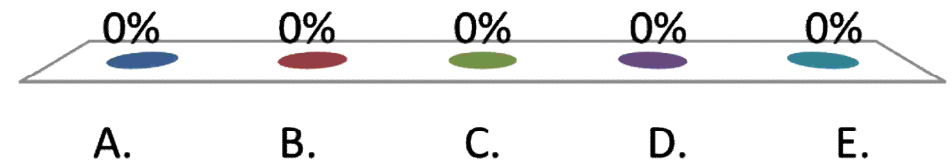


# Establishment Registration: Who Must Register

- What establishment types do NOT need to register?
  - Establishments engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device being investigated under IDE
  - Domestic distributor that does not import devices
  - Import agent, broker, and other parties who do not take first possession of a device imported into the United States
  - Manufacturer of components, that are not otherwise classified as a finished device, that are distributed only to a finished device manufacturer
  - Refurbishers or remarketers of used devices already in commercial distribution in the U.S.
  - Specification consultant only
  - Wholesale distributor that is not a manufacturer or importer

# POLL: Which Entity is Not Required to Register?

- A. Foreign Manufacturer of Device Accessories
- B. Entity Maintaining Device Complaint Files
- C. Domestic Manufacturer for Export Only
- D. Remarketer of Used Device
- E. Specification Developer



# POLL: Which Entity is Not Required to Register?

**(D) Remarketer of Used Device**



# Establishment Registration: When to Register

- **Initial Registration:** within 30 days of commencing device operations
- **Annual Registration:** between Oct. 1 and Dec. 31 of each year
  - \$4,624 User Fee in FY 2018
  - No reduced small business fee
- **Update Registration:** within 30 days of relevant changes
- *See 21 C.F.R. § 807.22.*

# Device Listing: Overview

- Authority derived from **Federal Food, Drug, & Cosmetic Act (21 U.S.C. § 360(j))**
- Listing regulation grouped with registration regulation: 21 C.F.R. Part 807

**(j) Filing of lists of drugs and devices manufactured, prepared, propagated and compounded by registrants; statements; accompanying disclosures**

(1) Every person who registers with the Secretary under subsection (b), (c), (d), or (i) of this section shall, at the time of registration under any such subsection, file with the Secretary a list of all drugs and a list of all devices and a brief statement of the basis for believing that each device included in the list is a device rather than a drug (with each drug and device in each list listed by its established name (as defined in section 352(e) of this title) and by any

# Device Listings: Who Must List

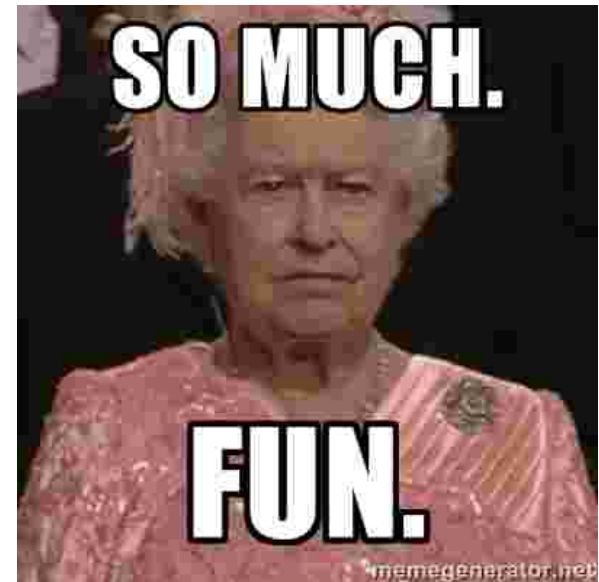
- 21 C.F.R. § 807.20:
  - Generally, all domestic and foreign establishments that are required to register are also required to submit listing information for devices in commercial distribution
  - Exception: Initial Importers
    - May fulfill their listing obligation for any device for which they did not initiate or develop the specifications for the device or repackage or relabel the device by submitting the name and address of the manufacturer
    - Must be prepared to submit the proprietary name, if any, and the common or usual name of each device for which they are the initial importer

# Device Listing: When to List

- **Initial Listing**
  - List devices at time of initial registration (w/in 30 days)
- **Annually**
  - Listing accuracy should be confirmed every year between October 1 and December 31
- **Whenever Changes Occur**
  - E.g., when a device is removed from distribution, change in labeling
- See 21 C.F.R. § 807.22

## **POLL: When is an Initial Importer Required to Update its Device Listings?**

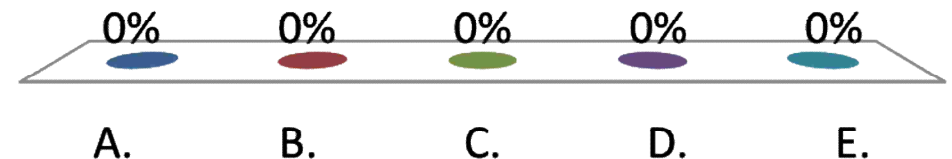
- (A) When it first registers as a device establishment**
- (B) Annually**
- (C) Whenever there are changes to listing information**
- (D) All of the above**
- (E) None of the above**





# POLL: When is an Initial Importer Required to Update its Device Listings?

- A. When it first registers as a device establishment
- B. Annually
- C. Whenever there are changes to listing information
- D. All of the above
- E. None of the above



# POLL: When is an Initial Importer Required to Update its Device Listings?

**(E) None of the above**



# Establishment Registration: How to Register

- First, Pay User Fees
  - Device user fees were first established in 2002 by the Medical Device User Fee and Modernization Act (MDUFMA).
  - User fees were most recently renewed in 2017 with the Medical Device User Fee Amendments to the FDA Reauthorization Act (MDUFA IV), which will be in place until Sept. 30, 2022.



# Establishment Registration: How to Register

- Pay User Fees
  - Register for the user fees system online
  - Fill out the MDUFA User Fee Cover Sheet (Form FDA-3601) online
  - Submit payment
    - Click the “Pay Now” button and follow the on-screen instructions to submit an online payment; OR
    - Send wire transfer; OR
    - Send printed copy of the completed cover sheet along with a check, bank draft, or U.S. Postal money order

# Establishment Registration: User Fee System



## Useful Links

- [User Fee Information](#)
- [User Fee Payment Information](#)
- [Frequently Asked Questions \(FAQs\)](#)
- [FDA User Fee Account Creation: Step-by-Step Instructions](#)
- [MDUFA 510\(k\) Cover Sheet Creation: Step-by-Step Instructions](#)
- [MDUFA 513g Cover Sheet Creation: Step-by-Step Instructions](#)

## Log in to the User Fee System

User Name:	Password:
<input type="text"/>	<input type="password"/>
<input type="button" value="Login"/>	<a href="#">Forgot User Name/Password?</a>

[New User? Please register...](#)

## User Fee System Alerts

*Effective October 1, 2010, FDA implemented new procedures for payment of the MDUFA Annual Fee for Periodic Reporting. As a result, customers are no longer able to create a User Fee Cover Sheet to pay their Annual Fee for Periodic Reporting.*

# How to Register and List

## Information Required (21 C.F.R. § 807.25, 807.40, 807.41):

- Payment Identification Number (PIN)
  - Receive this online after completing the cover sheet
- Payment Confirmation Number (PCN)
  - Receive this in e-mail after payment is processed
- Owner/operator information
  - Company name, address, telephone, e-mail, DUNS number
- Name and contact information for official correspondent
- Facility name, address, DUNS number
- Facility business trade names
- Activities performed by facility
- If foreign facility, name and contact information for U.S. agent, names and contact information for all importers
- Manufacturer's name and registration number
  - If you are not the manufacturer of the device
- All proprietary names for device(s)
- Device classification code and class
- 510(k)/DEN/PMA/HDE number, if applicable



# Establishment Registration:

## FDA's Unified Registration and Listing System (FURLS)

The screenshot displays the FDA Industry Systems website. At the top, it features the U.S. Department of Health and Human Services logo and the FDA OAA logo. The main heading is "ONLINE ACCOUNT ADMINISTRATION (OAA)". Below this, there is a "System Status" button. A news section titled "FDA Industry Systems" contains two entries: one dated 09/19/2017 regarding revised guidance for tobacco establishments, and another dated 09/12/2017 regarding tobacco registration and product listing for manufacturers impacted by natural disasters. The "Login" section includes fields for "Account ID" and "Password", with a note that existing account holders should enter their account ID and password. The "Getting Started" section provides instructions on how to create a new account and what to do if you already have an account. A warning message states that the system is a U.S. Government information system and its use is monitored and recorded. A final note asks if the user's computer is secure and encourages users to secure their computers before using the system.

U.S. Department of Health and Human Services

**FDA**  
OAA

**ONLINE ACCOUNT  
ADMINISTRATION (OAA)**

FDA Industry Systems [System Status](#)

09/19/2017: See [FDA published the revised guidance, Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments. Click here for details.](#)

09/12/2017: See [Information regarding Tobacco Registration and Product Listing for manufacturers impacted by recent natural disasters. Click here for details.](#)

**Login**

Existing account holders, enter your account ID & password

Account ID

Password

*Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.*

**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" towards the bottom left side of this page.

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 all users

# Establishment Registration: FURLS

Account Management

Account Management ID

Welcome to the FDA Industry Systems. You are logged in as **san1169** for **SANCO**.

You may choose an option on the left to manage your account or select an FDA system below. To obtain access to available FDA systems, choose the **Update System Access** option to add the FDA system to your account.

CDRH - Center for Device and Radiological Health

Click to launch the Application(s)

- Device Registration and Listing Module
- Laboratory Developed Test Notification
- CDRH Export Certification Application and Tracking System



# Establishment Registration: DRLM

The screenshot shows the 'Register a Device Facility' page in the DRLM system. At the top left is the 'DRLM Device Registration & Listing Module' logo. At the top right is the FDA logo with the text 'FDA FOR YOU'. The main heading is 'Register a Device Facility' with a 'Get help' link. Below the heading is a table with columns: 'Select', 'Name and Address', 'Status', and 'Registered in Module'. The table contains one entry with the following details:

Select	Name and Address	Status	Registered in Module
<input type="checkbox"/>	SANCO 12345 Street Lane Atlanta, Atlanta, 30302, UNITED STATES	Active (Being An- Registration Number Assignment)	

At the bottom of the page are three buttons: 'RETURN TO MAIN MENU', 'UPDATE REGISTRATION', and 'REGISTER A NEW FACILITY'. The 'UPDATE REGISTRATION' and 'REGISTER A NEW FACILITY' buttons are highlighted with orange boxes. Two callout boxes provide instructions:

- Update Registration:** If the facility you wish to register is being displayed, select the facility and then click "Update Registration".
- Register a New Facility:** If the facility you wish to register is not being displayed, click on "Register a New Facility".

# Device Listing: How to List

Register Your Facility  
**Identify Facility's Products** Get Help: ?

**FACILITY: SANCO, ROCKVILLE, MARYLAND, UNITED STATES**

**Important Notice:** You must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you have not yet received your Payment Confirmation Number (PCN), you will not be able to register your facility or enter any information you have entered and will need to re-visit and re-enter all information for the facility.

The products shown below have previously been listed by your company for other facilities. Select one or more products from the list below for this Facility or click "ADD NEW PRODUCT" to create a listing for a new product.

<input type="checkbox"/>	Listing Number	Listing Status	Premarket Submission Number/Type	Product Code(s)	Device Name	Registration Number
<input type="checkbox"/>	D123456	Active	Exempt	702	HANDLE SCALPEL	Not YET Assigned
<input type="checkbox"/>	D123457	Active	Exempt	200	HYDRAZONE COLORIMETRY, ALT/SOFT	Not YET Assigned

Click on this button if no existing listings match the new facility's devices

Click this button if you have selected any listings that match the new facility's devices.

# Device Listing: How to List

The screenshot shows a web form titled "New Listing Product Code". The form contains several input fields and a table. The "FACILITY" field is populated with "UNIVERSITY MICROFILMS INTERNATIONAL". Below it is a large text area with a placeholder for a description. Further down is a "PARENT" dropdown menu. At the bottom of the form is a table with five columns: "Product Name", "Product Code", "Description", "Date", and "Product Category". The table lists several product codes, with the last one, "UNIVERSITY MICROFILMS INTERNATIONAL", highlighted in blue. At the bottom of the form are three buttons: "Back", "Cancel (CTRL+SHIFT+ESC)", and "Save".

Product Name	Product Code	Description	Date	Product Category
UNIVERSITY MICROFILMS INTERNATIONAL	001	UNIVERSITY MICROFILMS INTERNATIONAL	1	UNIVERSITY MICROFILMS INTERNATIONAL
UNIVERSITY MICROFILMS INTERNATIONAL	002	UNIVERSITY MICROFILMS INTERNATIONAL	2	UNIVERSITY MICROFILMS INTERNATIONAL
UNIVERSITY MICROFILMS INTERNATIONAL	003	UNIVERSITY MICROFILMS INTERNATIONAL	3	UNIVERSITY MICROFILMS INTERNATIONAL
UNIVERSITY MICROFILMS INTERNATIONAL	004	UNIVERSITY MICROFILMS INTERNATIONAL	4	UNIVERSITY MICROFILMS INTERNATIONAL
UNIVERSITY MICROFILMS INTERNATIONAL	005	UNIVERSITY MICROFILMS INTERNATIONAL	5	UNIVERSITY MICROFILMS INTERNATIONAL
UNIVERSITY MICROFILMS INTERNATIONAL	006	UNIVERSITY MICROFILMS INTERNATIONAL	6	UNIVERSITY MICROFILMS INTERNATIONAL
UNIVERSITY MICROFILMS INTERNATIONAL	007	UNIVERSITY MICROFILMS INTERNATIONAL	7	UNIVERSITY MICROFILMS INTERNATIONAL

# Device Listing: How to List

The image shows a screenshot of a web form for adding proprietary names to a device listing. The form includes several sections and callout boxes:

- Proprietary Name:** A text input field with a callout box: "Added proprietary names will display here."
- Confidentiality:** A checkbox labeled "This name needs to be kept confidential" with a callout box: "Click this box if the proprietary name needs to be kept confidential."
- Additional Names:** A section with a callout box: "Enter proprietary names here. Then click 'Add Proprietary Name.' Repeat for each proprietary name."
- Notes:** A text area with a callout box: "Do not enter information in this section, unless you are part of the Pilot Program."
- Buttons:** "Add Proprietary Name" and "CLEAR" buttons.
- Spreadsheet Option:** A section titled "Upload Proprietary Names Using Spreadsheet" with a callout box: "If you have a large list of proprietary names, you can use the option for uploading them in a spreadsheet."

# Establishment Registration

- You will receive an e-mail from the FDA confirming submission of the registration
  - “Your device establishment is now considered registered”
- The company will receive its official registration number from the FDA within 90 days

# Device Listing: Additional Considerations

- **Maintain Historical File**
  - 21 C.F.R. § 807.26
  - Labeling for listed device (advertising, too, if it is a restricted device)
    - In use at time of listing
    - Any labeling or advertisements in which a material change has been made anytime after initial listing
  - Can discard three years after device is discontinued
- **Public Availability**
  - 21 C.F.R. § 807.37
  - Listing information (and registration information) generally available to the public on the FDA's website
  - Except: information revealing confidential business relationships, FDA-assigned listing numbers

# Common Mistakes

- “I do not need to register or list because my product is not a medical device”
- Initial analysis regarding regulatory status important
  - 21 U.S.C. § 321(h)

(h) The term “device” (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

## Common Mistakes (cont'd)

- “I am not a manufacturer, so there is no need for me to register as a medical device establishment”
  - WRONG. See 21 C.F.R. § 807.20
- Forgetting to pay user fees first
- The foreign manufacturer did not list the initial importer in the U.S.



## Common Mistakes (cont'd)

- “I can state that my establishment is FDA registered or use my registration number in advertising to consumers”
  - Not if it creates an impression of official FDA approval
  - 21 C.F.R. § 807.39



# Common Mistakes (cont'd)

- FDA also regulates radiation-emitting electronic products
  - E.g., Ultrasound, UV light, lasers, infrared heat, radiofrequency, X-ray, magnetic
    - 21 U.S.C. §§ 360hh - 360ss
    - 21 C.F.R. Parts 1000 to 1050
- Separate, *additional*, requirements for radiation-emitting products
  - May be subject to requirement to submit a “product report”
  - Products may be held at border on import



# QUESTIONS???

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