Establishment Registration and Device Listing

Michelle C. Jackson, Esq.
Partner
Venable LLP

FDLI

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 <u>any foreign country</u> 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

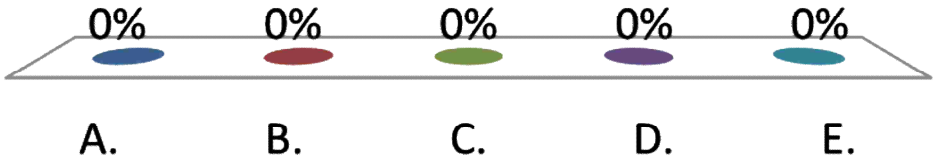
Establishment Type	Applicable Regulation
Manufacturer of a custom device	21 C.F.R. § 807.20(a)(2)
Relabeler or Repackager	21 C.F.R. § 807.20(a)(3)
Remanufacturer	
Reprocessor of single use devices	21 C.F.R. § 807.20
Specification developer	21 C.F.R. § 807.20(a)(1)
U.S. manufacturer of export only devices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

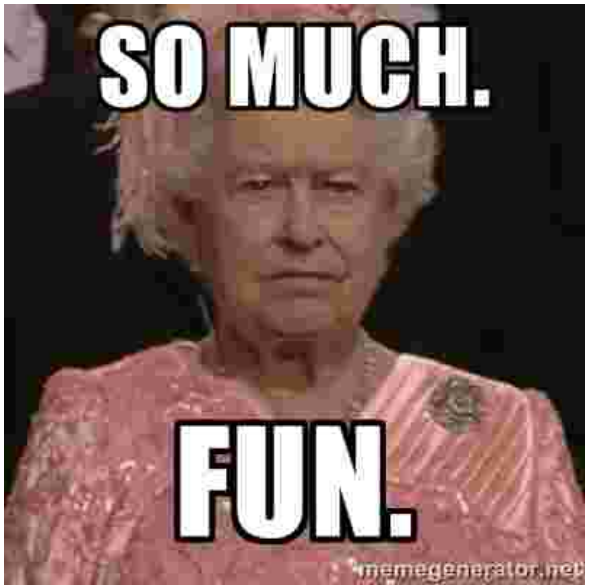
- 21 C.F.R. § 807.20:
  - Generally, all domestic and foreign establishments that are required to register are also required to submit listing information for devices in commercial distribution
  - Exception: Initial Importers
    - May fulfill their listing obligation for any device for which they did 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



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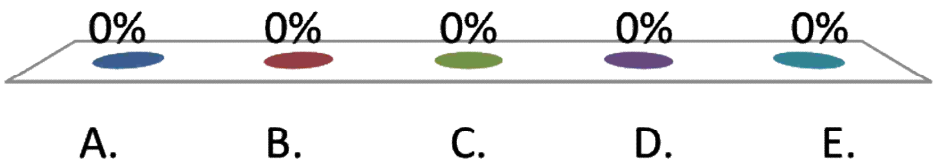

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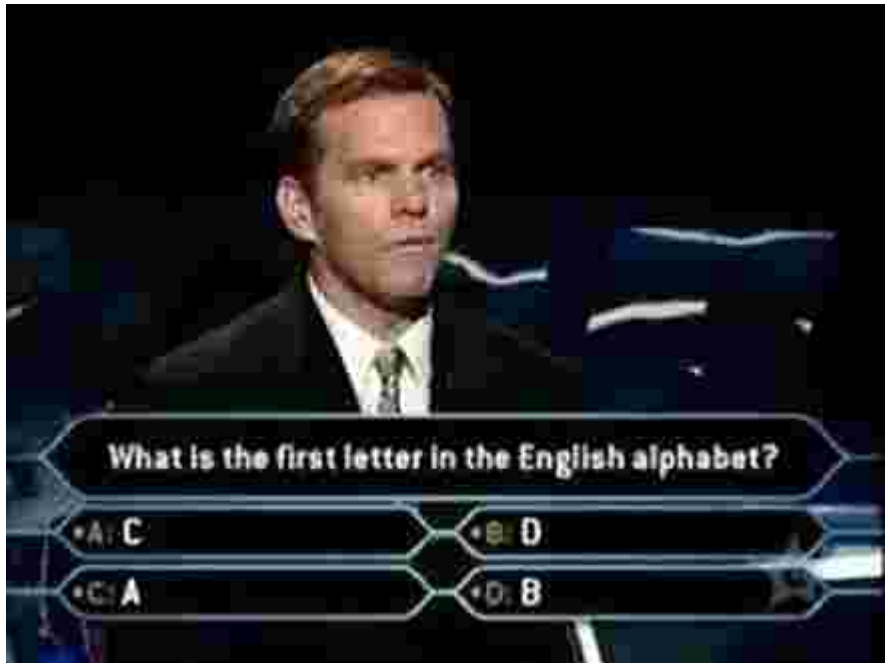


Establishment Registration: How to Register

- 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

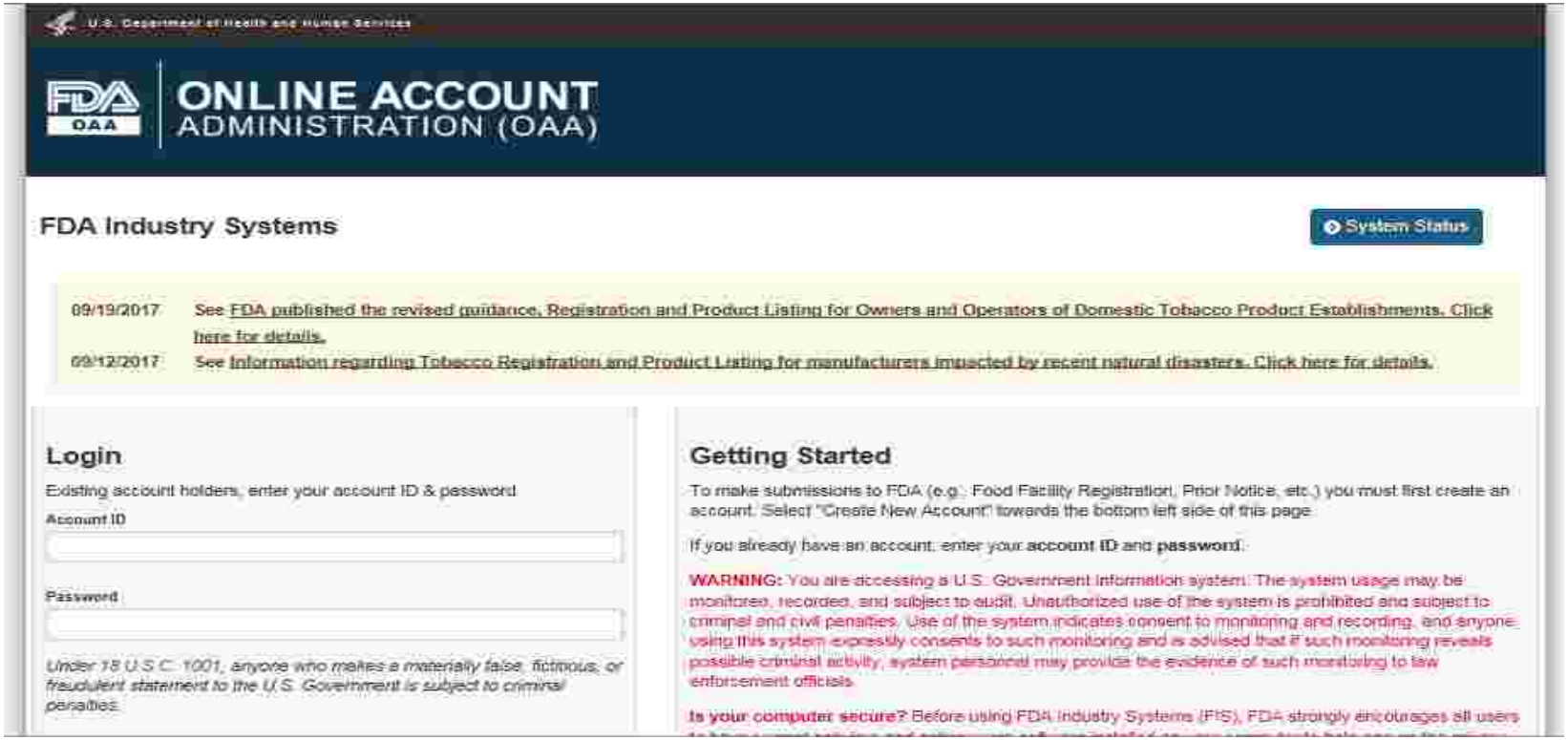
How to Register and List

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

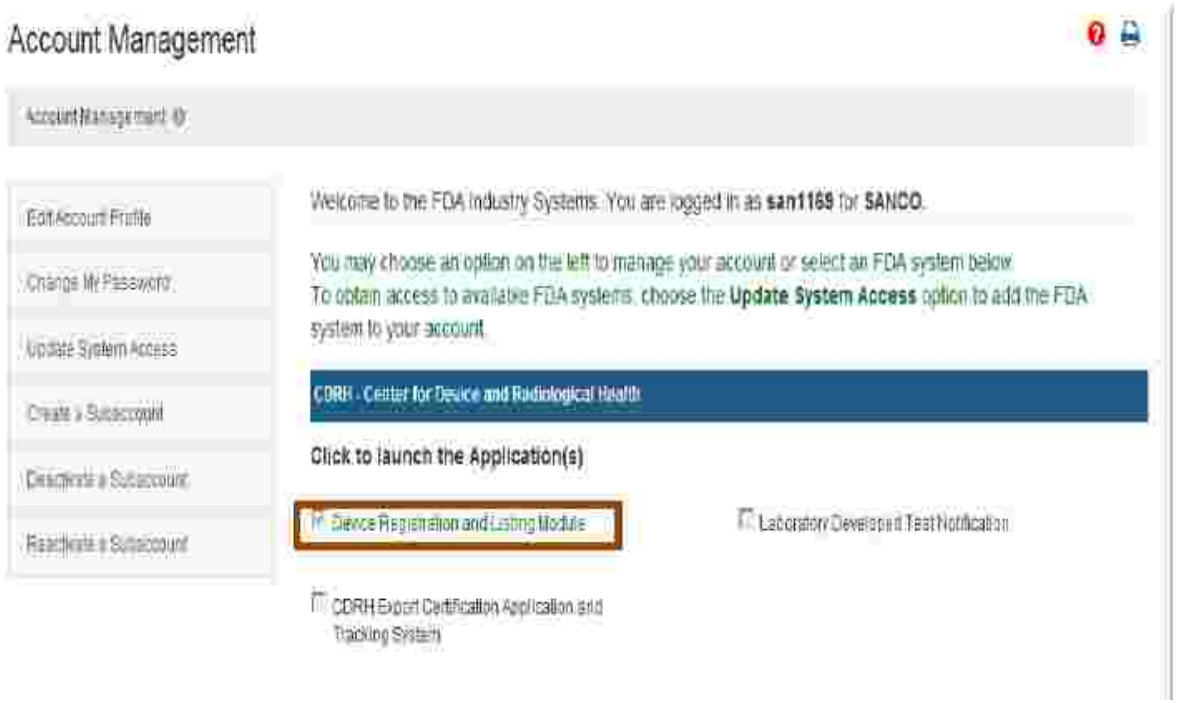
- Payment Identification Number (PIN)
  - Receive this online after completing the cover sheet
- Payment Confirmation Number (PCN)
  - Receive this in e-mail after payment is processed
- Owner/operator information
  - Company name, address, telephone, e-mail, DUNS number
- Name and contact information 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:

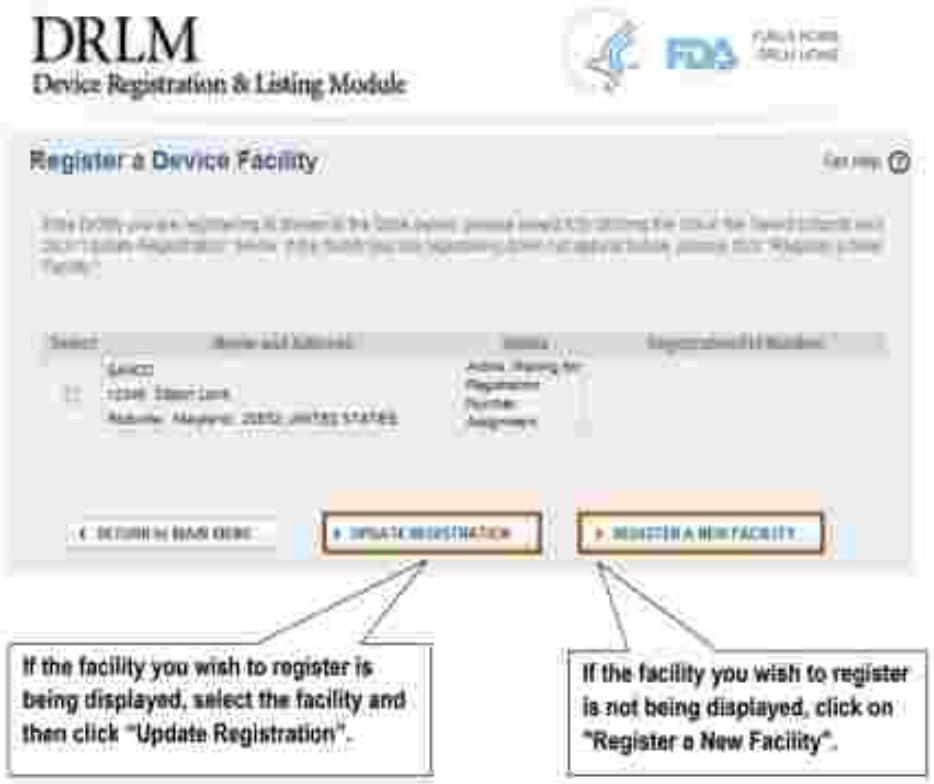
FDA's Unified Registration and Listing System (FURLS)



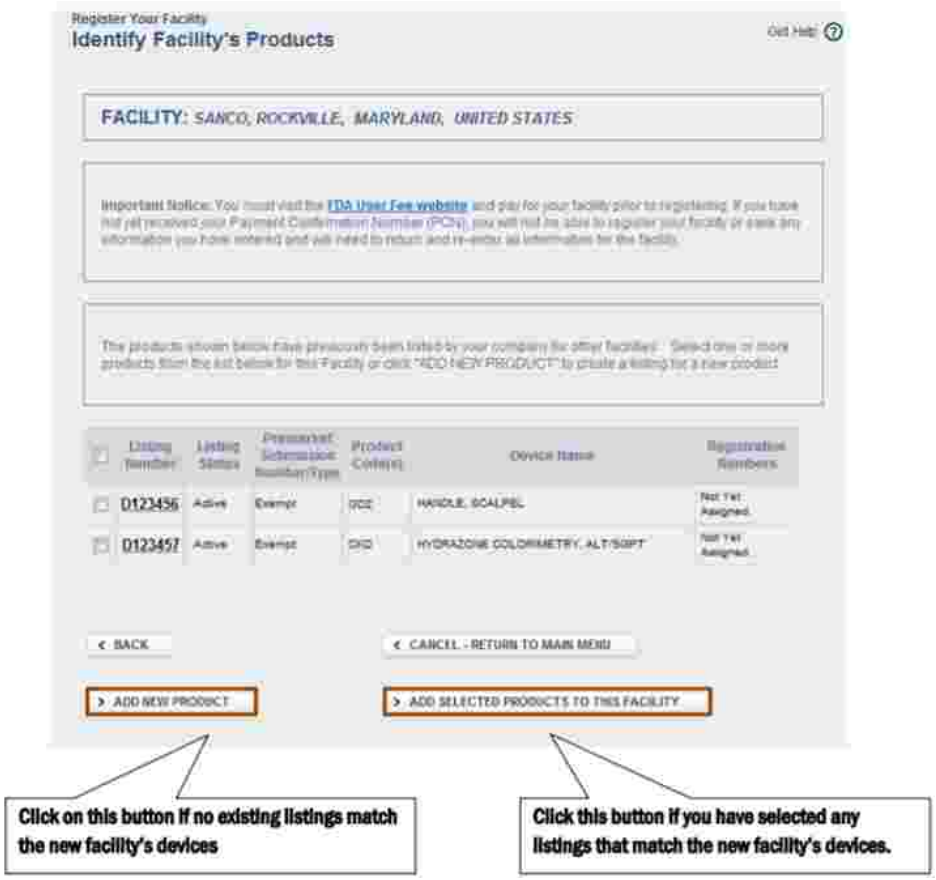
Establishment Registration: FURLS



Establishment Registration: DRLM



Device Listing: How to List



Device Listing: How to List

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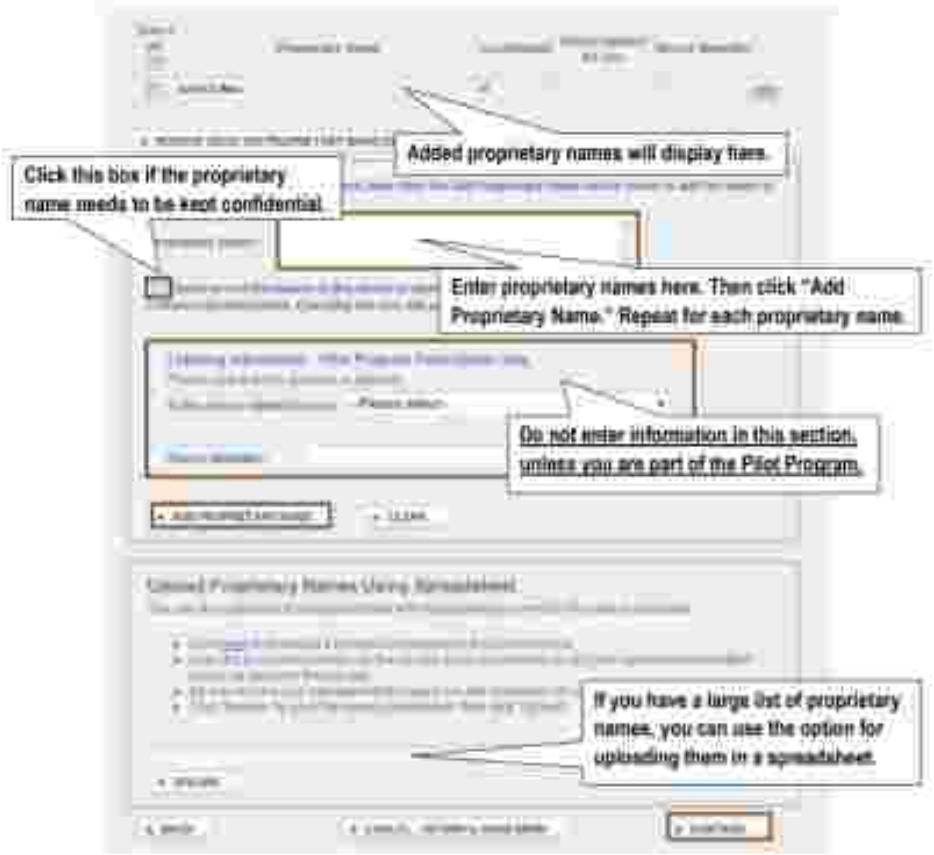

Establishment Registration

- 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???

Michelle C. Jackson, Esq.
Venable LLP
202.344.4492
MCJackson@Venable.com

FDLI