

FDA Registration and Listing Process

FDA Small Business Regulatory Education for Industry (REdI)

June 8, 2022

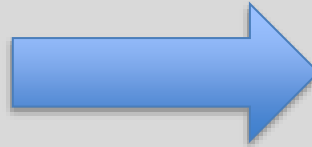
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“Why should you listen to me?”

“So I can provide you with information to save
time and frustration”

From



To





Imports and Registration & Listing Team

Learning Objectives

- Review registrations and listing regulatory history
- Summarize registration and listing information
- Walk through registration and listing examples

Registration and Listing Regulatory History

Regulatory Authority

FD&C (1976)

- Section 510 of Federal Food, Drug and Cosmetic Act
- Requires medical device establishments to register and list

FDAAA (2007)

- Food and Drug Administration Amendments Act
- Mandated use of an electronic registration and listing system
- Introduced user fees for many establishment types

Regulatory Authority, cont.



FDASIA (2012)

- Food and Drug Administration Safety and Innovation Act
- Expanded user fee to all establishment types

21 CFR 807 (2012)

- Explains specific regulatory registration and listing requirements
- Revised regulations effective October 1, 2012 for Fiscal Year 2013

Overview of Revised Establishment and Device Regulation For FY2013



All Establishments must pay the annual registration user fee

Proprietary Names are Required

Initial importers must identify manufacturers of products

Foreign manufacturers exporting products must identify importers

Contract Manufacturers and Sterilizers are required to R&L

Establishments must identify the type of combination products

Manufacturer or specification developer must list before contract others can list

Complaint Filers also must register and list

Registration and Listing Information

Who is Required to Register and List

Establishment Type	Domestic	Foreign
Manufacturers / Remanufacturers / Kit Assemblers	Yes	Yes
Specification Developers	Yes	Yes
Contract Manufacturers / Sterilizers	Yes	Yes
Repackagers / Relabelers	Yes	Yes
Reprocessors of Single-Use Devices	Yes	Yes
Complaint File Establishment per 21 CFR 820.198	Yes	Yes
Initial Importers	Yes	N/A

www.fda.gov/medical-devices/device-registration-and-listing/who-must-register-list-and-pay-fee

When to Register

- Domestic Establishments:
 - Within **30 days** after entering into activity
- Initial Importers:
 - Prior to importing a medical device
- Foreign Establishments:
 - Prior to devices being imported or offered for import into the United States

For additional information, visit [When to Register and List](#)

Annual Registration Information



- Annual Registration Period: October 1st – December 31st
- Device Listings must be updated
- Non-exempt products must include 510(k), PMA, HDE or NDA number(s)
- PMA exempt product codes should be listed under 1 product code
- Identify all proprietary or brand names under which the product is marketed

Initial Registration Information



- Create an account using [Device Facility User Fee](#) to obtain a PIN
- Pay the annual/initial user fee (\$5,672 for FY2022)
- Establishment will receive a PCN once payment is processed
- Create an account to register the establishment using [FURLS/DRLM](#)
- Provide accurate establishment information

For Additional Information, visit: [How to Register and List | FDA](#)

Reactivate or Deactivate a Registration



- To reactivate a registration for the establishment will need to pay the user fee using DFUF
- Once the PIN/PCN is received, the reactivation can be processed
- Zero fees for deactivating registrations

For more Information on Reactivation of Registrations
visit [Reactivation of Registrations](#)

Initial Importers vs. Importers

Initial Importers

- Any importer who furthers marketing of a device from a foreign manufacturer to person who makes final delivery or sale of device to ultimate consumer or user
- Do not repackage, or otherwise change the container, wrapper, or labeling of device or device package.

Importers

- End user(s) of regulated medical device(s) not furthering marketing of a device(s) or are importing regulated medical device(s) to be sold to end user(s).
- Importers are exempt from registration requirements

Resources and Recap

Knowledge Check

When do foreign establishments need to register and list with FDA?

1. They don't need to
2. Prior to offering regulated medical devices for import into the United States
3. When they begin manufacturing medical devices

Knowledge Check

When does the Annual Registration Period start?

1. October 1st
2. December 31st
3. June 8th

Knowledge Check

Does FDA provide a user fee discount for small businesses?

1. Yes
2. No

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- CDRH IRLT Mailbox, Device.reg@fda.hhs.gov

Resources



Slide #	Cited Resource	URL
11	When to Register and List	www.fda.gov/medical-devices/device-registration-and-listing/when-register-and-list
13	Device Facility User Fee	userfees.fda.gov/OA_HTML/furls.jsp
13	FURLS/DRLM	www.access.fda.gov/drlm/help/index.html
13	How to Register and List	www.fda.gov/medical-devices/device-registration-and-listing/how-register-and-list#4
14	Reactivating of Registrations	www.fda.gov/medical-devices/device-registration-and-listing/how-register-and-list#8

Summary

- FDA has regulatory authority involving registration and listing
- Different requirements for initial and annual registration
- Process for setting up an account

Questions

