

Welcome To Today's Webinar

Thanks for joining us!
We'll get started in a few minutes

Today's Topic: Registration & Listing Requirements for In Vitro Diagnostic Products (IVDs), Including Laboratory Developed Tests (LDTs)

December 3, 2024

Registration & Listing Requirements for In Vitro Diagnostic Products (IVDs), Including Laboratory Developed Tests (LDTs)

Kimberly Kopecki

Senior Policy Advisor
Office of the Center Director

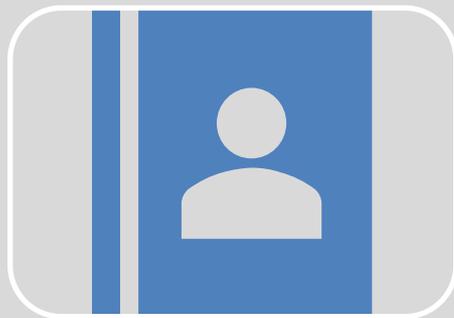
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Learning Objectives

- Review phaseout policy Stage 2 compliance expectations related to registration and listing
- Identify which establishments need to register
- Explain how user fees are paid
- Discuss how to register an establishment and list devices



Phaseout Policy: Stage 2



Establishment Registration & Device Listing

(21 CFR pts. 607, 807 subparts A-D)

Establishment Registration information provides FDA with the location of device establishments and all devices manufactured at those establishments.

Device Listing information provides FDA, patients, and providers information on the universe of IVDs on the market.

Do I Need to Register?

Establishment

A place of business or other entity under one management at **one general physical location** that performs activities on products subject to FDA regulation

21 CFR 807.3(c); see also 21 CFR 607.3(c)



Single vs Multiple Sites



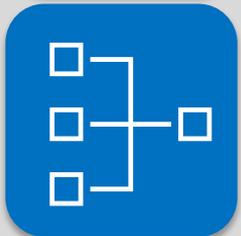
One Geographic Location

...includes separate buildings within close proximity if the activities in them are closely related to the same business enterprise, under the supervision of the same local management, and are capable of being inspected at the same time.



Close Proximity

- Within a campus setting
- Within three miles driving distance of each other
- The buildings MUST be within the same State and the same United States Judicial District Court area



Quality System

- Operating under the same Quality Management System

Enforcement Discretion

FDA intends to generally **not** enforce registration and listing requirements for the following tests:



“1976-Type LDTs”

Tests that have the following characteristics common among LDTs offered in 1976

- use of manual techniques (without automation) performed by laboratory personnel with specialized expertise
- use of components legally marketed for clinical use
- design, manufacture, and use within a single CLIA-certified laboratory that meets the requirements under CLIA for high complexity testing



Certain Human Leukocyte Antigen (HLA) Tests for Transplantation

HLA tests that are designed, manufactured, and used within a single laboratory certified under CLIA that meets the requirements to perform high-complexity histocompatibility testing when used in connection with organ, stem cell, and tissue transplantation to perform HLA allele typing, for HLA antibody screening and monitoring or for conducting real and “virtual” HLA crossmatch tests.



Forensic Tests

Tests intended solely for forensic (law enforcement) purposes.



Department of Defense (DoD) and Veterans Health Administration (VHA) LDTs

LDTs manufactured and performed within the DoD or VHA. This policy applies only to LDTs used for patients that are being tested and treated within the DoD or VHA.



Public Health Surveillance Tests

Tests manufactured and offered for use exclusively for public health surveillance

When Do I Need to Register?

Initial

By May 6, 2026

OR

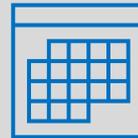
within 30 days of an establishment
beginning an activity or putting a
device into commercial
distribution*



Annual

Complete annually, between
October 1 – December 31 of
each year

See 21 CFR 807.22 for information
on annual registration and when to
file updates



Establishment Registration and Device Listing Steps for Initial Registration



Tutorial: www.accessdata.fda.gov/cdrh_docs/presentations/FURLS/story.html

DFUF: Device Facility User Fee Website
FURLS: FDA Unified Registration and Listing System
DRLM: Device Registration and Listing Module
PIN: Payment Identification Number
PCN: Payment Confirmation Number

Pay the Establishment Registration User Fee in DFUF Website



Create an account on the Device Facility User Fee (DFUF) website to pay the Establishment registration user fee:

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

Submit your order in the DFUF website and obtain PIN:

✦ PIN starts with 50xxxxx

PCN will be sent to you by email when payment is processed.

↔ PCN starts with 25xxxxx

Tutorial: www.accessdata.fda.gov/cdrh_docs/presentations/AnnualFee/index.html

Current Fiscal Year User Fees: www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing

PIN: Payment Identification Number

PCN: Payment Confirmation Number

DFUF: Device Facility User Fee Website



Pay the Establishment Registration User Fee in DFUF Website



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

U.S. Department of Health & Human Services
FDA U.S. Food and Drug Administration
Protecting and Promoting Your Health

change its policies regarding the transfer of payments across fiscal years to align with the Treasury Accounting Treatment Manual. The Agency will refund payments made to user fee cover sheet ID that are any payment from a prior year without a corresponding application submission should submit a refund request. To request a refund, complete [Form FDA 3913](#) and email the form to CDERCollections@fda.hhs.gov at <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UC1492188.pdf>.

cover sheet within the FY that is not linked to an application submitted in that FY will not be transferred to the new FY. Previous FY payment without an application submission will be refunded and the payment for the new FY.

Y will not be affected by this change in policy. If you have any questions regarding this change, please contact the User Fee Staff at userfees@fda.gov.

Log in to the User Fee System
[Login to Enterprise ICAM](#)
[Forgot User Name/Password?](#)
New User? Please register...

User Fee System Alerts

New User Registration

The FDA Division of User Fees has partnered with Dun & Bradstreet (D&B) to allow new FDA User Fee customers to locate their organization in the D&B database. If your organization's information is found in the D&B database, it will be pre-populated as you complete the User Fee Website registration process.

To locate your organization, please provide the information requested below, and click the "Go" button. Fields marked with an asterisk are required. **After performing a search, scroll down to view and/or select from the Search Results.**

After performing your search, if you cannot locate your organization in the D&B database, please select the "I am a new Organization" option to manually input your organization's information.

Business Name *
DUNS Number
Country *
City *
State *

Search Results

Your search did not produce any results. Please perform a new search or go to www.dnb.com to register your business and get a D&B D-U-N-S Number.

Otherwise, please select the "I am a new Organization" option to manually input your organization's information.

Organization Name	Address	DUNS	Action
<input type="text" value="I am a new Organization"/>			<input type="button" value="Select"/>



Pay the Establishment Registration User Fee in DFUF Website



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

U.S. Department of Health & Human Services
FDA U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Confirmation
Successfully completed registration process for FDA Userfee System. Please Click here to [Login](#)

U.S. Department of Health & Human Services
FDA U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

User Fee Website

Welcome FDA Test User

Annual Establishment Registration	
User Fee	Description
MDUFA Establishment Registration User Fee 2024	FURLS Device Facility User Fee

Device facility User Fee

All medical device establishments/facilities that are required to register with the FDA are required to pay the Device Facility User Fee. Section 737 (21 U.S.C. 379f) paragraph 13 states that the term 'establishment subject to a registration fee' means an establishment that is registered (or is required to register) with the Secretary under section 510 because such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of a device.

For additional information, please refer to:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm>

** If you have both domestic and foreign facilities, please make sure to go through this process for each facility.

The 2024 registration process includes 3 main steps:

1. **Create your order and PIN (payment identification number)** - you are here
2. **Pay**
3. **Register**

You must complete the entire payment and registration process by December 31, 2023. Please provide enough time payment processing especially if you are paying by check.

The annual registration user fee is paid by Fiscal Year. The Fiscal Year runs from October 1st to September 30th each year. When you register your establishment, the registration is valid until September 30th, but will remain active until December 31st in order for you to register for the next Fiscal Year. For example, if you register on October 1st, 2023, the registration will be valid until September 30th, 2024 but remain active until December 31st, 2023. Please note that registering at a later date neither changes the registration fee amount or the date that the registration is valid for. There is no reduction in the fee for small businesses or any other groups.

Product	Quantity	Unit Price
Device Facility User Fee	1	\$7,653.00 EACH

[Add to Cart](#)



Pay the Establishment Registration User Fee in DFUF Website

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

Please review the important message below regarding a change in policy on payment transfer

At the end of fiscal year (FY) 2020, FDA will change its policies regarding the transfer of payments across fiscal years. Agency will refund payments made to user fee cover sheet ID that are not linked to a submitted establishment registration with any payment from a prior year without a corresponding registration should submit a refund request. To request a refund, please email userfees@fda.gov. Form FDA 3913 is available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/3913.pdf>.

Starting in FY 2021, a payment made to a user fee cover sheet within the FY that is not linked to a registration submission will be refunded and the medical device establishment/facility will have to submit a new FY.

Payment transfers occurring within the same FY will not be affected by this change in policy. If you have any questions regarding this change, please contact the User Fee Staff at userfees@fda.gov.

Device Facility User Fee

Confirmation
Your order has been submitted electronically. The preferred payment method is online using a credit card or electronic check (ACH). If you are paying by check, please write your Payment Identification Number (PIN) on your check. For additional payment information, click on the link "What are my payment options?" below.

Thank you for visiting the FDA User Fee Website. As part of our efforts to improve customer service, we would like to hear from you. Please [click here](#) to fill out a short survey. This will only take approximately 2 minutes to complete.

Product	Quantity	Creation Date	Last Update Date	Unit Price
FY 2024 Device Facility User Fee Print/View Final Order	1	25-MAR-2024 10:34:23	25-MAR-2024 10:38:51	\$7,653.00
Total:				\$7,653.00

YOUR PAYMENT IDENTIFICATION NUMBER (PIN) IS:
50422972

[What are my payment options?](#)

[User Fees](#) | [Order](#) | [Previous Orders / PCN](#) | [Profile](#) | [Logout](#)



Create an Account in FURLS/DRLM



All establishment registration information is submitted electronically using the FDA Unified Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM)

Create an account for FURLS at:

www.access.fda.gov/oa/logonFlow.htm?execution=e1s1

Under New User, click Create Account

Tutorial: www.fda.gov/food/online-registration-food-facilities/fda-industry-systems-account-management-guide



Create an Account in FURLS/DRLM



<https://www.access.fda.gov/oaa/logonFlow.htm?execution=e2s1>

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.

I understand.

[Login](#) [Forgot Account ID](#) [Forgot Password](#)

New User

[Create New Account](#)

[See Instructions](#) [See Tutorials](#) [Help Desk](#)



FDA ONLINE ACCOUNT ADMINISTRATION (OAA)

Create New Account

Create New Account

You must create a separate account to create your Medical Device Registration and Listing or Food Facility.

Step 1: Select Application(s) for Account Creation

Do you conduct work for a State Agency under Contract with the FDA?
If you are creating an account on behalf of a manufacturer, please select "No."

Yes No

Registration and Listing Programs

Food

Acidified/Low-Acid Canned Foods Registration and Process Filing Export Listing Module

Food Facility Registration Shell Egg Producer Registration

Qualified Facility Attestation

Medical Devices

Device Registration and Listing Module

Create Initial Registration in FURLS/DRLM

Click on Device Registration and Listing Module. Click on Register a New Medical Device Facility. Provide the required information for the establishment



Establishment, owner operator, and official correspondent

Name, address, phone number, and email address for each of above contacts

Establishment website address, if any

Trade names used by establishment

Tutorial: www.access.fda.gov/drlm/help/RegisterANewMedicalDeviceFacility.html



Register a New Medical Device Establishment in FURLS/DRLM



U.S. Department of Health and Human Services

FDA OAA | **ONLINE ACCOUNT ADMINISTRATION (OAA)**

Account Management

Account Management

- Edit Account Profile
- Change My Password
- Update System Access
- Create a Subaccount
- Deactivate a Subaccount
- Reactivate a Subaccount

Welcome to the FDA Industry Systems.

You may choose an option on the left to obtain access to available FDA systems.

Registration and Listing Programs

Food

- Acidified/Low-Acid Canned Foods Registration and Process Filing
- Shell Egg Producer Registration

Medical Devices

- Device Registration and Listing Module

Export Certification and Tracking

- Biologics Export Certification Application and Tracking System (BECATS)

U.S. Department of Health and Human Services

FDA FURLS | **DRLM Device Registration**

DRLM Home

- Annual Registration
- Annual Registration
- Facility Registration**
- Register a New Medical Device Facility
- Change Registration Information for a Facility
- Cancel, Deactivate, or Reactivate a Facility Registration
- View Your Registration and Listing Information

Facility Information

Location Information

Same as Owner/Operator Same as Official Correspondent Clear

Check this box if this establishment is located in a foreign trade zone

Country / Area: Address Line 1:

Facility Name: Address Line 2 (Optional):

Phone (Optional): Country: Area: Phone Number: Extension:

Fax (Optional): Country: Area: Fax Number:

DUNS Number (Optional): Zip/Postal Code:

(Enter only the 9-digit number, no dashes or other characters)

Other Business Trade Name(s): City:

State/Province/Territory:

Facility URL (Optional): Facility URL (Optional):

The annual registration user fee is paid on a Fiscal Year



Create Device Listing in FURLS/DRLM



Facility: FDA, Silver Spring, Maryland, UNITED STATES

Enter the Premarket Submission Number

Facility: DRLM TEST 2023 OWNER UPDATEDfhjkhj, Mosby, Virginia, UNITED STATES

For the product you are listing, do you have one of the following ?

- Premarket Notification (510(k)) number
- De Novo (DEN) number
- Premarket Application (PMA) number
- Product Development Protocol (PDP) number
- Humanitarian Device Exemption (HDE) number
- Investigational New Drug (IND) number
- New Drug Application (NDA) number
- An IVD offered as an LDT and do not expect compliance with enforcement discretion policy described in the preamble to the final rule.

Yes No

Enter Premarket Submission Number

For the product you are listing, enter one of the following:

- Premarket Notification (510(k)) number
- De Novo (DEN) number
- Premarket Application (PMA) number
- Product Development Protocol (PDP) number
- Humanitarian Device Exemption (HDE) number
- Investigational New Drug (IND) number
- New Drug Application (NDA) number

If you are listing an IVD offered as an LDT and do not have a premarket submission number because under the phaseout policy described in the preamble to the LDT Final Rule, FDA does not expect compliance with premarket review requirements until stage 4 or 5 of the phaseout policy, or because the IVD falls within a targeted enforcement discretion policy described in the preamble to the final rule, please enter the code provided in the FDA's webinar on [Registration & Listing Requirements for In Vitro Diagnostic Products \(IVDs\) Including Laboratory Developed Tests \(LDTs\)](#) in the Premarket Submission Number box.

If you believe the product you are listing falls under enforcement discretion, preamendment, import for export or emergency please contact the CDRH Registration and Listing Helpdesk at reglist@cdrh.fda.gov.

If your device is exempt from FDA premarket notification requirements, leave the box empty.

If the product is a combination product, please check the Combination Product checkbox and then click "Next".

Premarket Submission Number (Optional)

2177

If at the time of listing, FDA generally does not intend to enforce compliance with premarket review requirements for the IVD offered as an LDT being listed, enter "2177" in the Premarket Submission Number field:

A list of policy specific product codes will be displayed

Policy Product Codes

SCE

IVD offered as LDT, first marketed before May 6, 2024, not modified beyond scope described in preamble to LDT Final Rule

Currently marketed in vitro diagnostic products (IVDs) offered as laboratory developed tests (LDTs) that were first marketed prior to May 6, 2024, and not modified following that date or not modified beyond the scope described in section V.B.3 of the preamble to the LDT Final Rule (89 FR 37286).

SCF

LDT, unmet need within an integrated healthcare system

Laboratory developed tests (LDTs) manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system as described in section V.B.3 of the preamble to the LDT Final Rule (89 FR 37286).

SCG

Modified version of another manufacturer's FDA-authorized test within scope described in preamble to LDT Final Rule

When a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and meeting CLIA's regulatory requirements to perform high complexity testing modifies another manufacturer's 510(k) cleared or De Novo authorized test, and in compliance as described in section V.C.3 of the preamble to the LDT Final Rule, in a manner that could not significantly affect the safety or effectiveness of the test and does not constitute a major change or modification in intended use, and where the modified test is performed only in the laboratory making the modification as described in sections V.C.4 and V.C.5 of the preamble to the LDT Final Rule (89 FR 37286).

Policy Product Codes

SCH

LDT, approved by NYS CLEP

Laboratory developed tests (LDTs) that are approved by the New York State Department of Health Clinical Laboratory Evaluation Program (NYS CLEP) described in section V.B.2 of the preamble to the LDT Final Rule (89 FR 37286).

SCI

IVD offered as LDT, not an LDT or under a targeted enforcement discretion policy described in preamble to LDT Final Rule

In vitro diagnostic products (IVDs) offered as laboratory developed tests (LDTs) that are not designed, manufactured, and used within a single laboratory, are within the scope of the phaseout policy and are not subject to a targeted enforcement discretion policy described in the preamble to the LDT Final Rule (89 FR 37286).

SCJ

LDT, not under a targeted enforcement discretion policy described in preamble to LDT Final Rule

Laboratory developed tests (LDTs) within the scope of the phaseout policy and not subject to a targeted enforcement discretion policy described in section V.B of the preamble to the LDT Final Rule (89 FR 37286).

SCK

LDT, Non-molecular antisera for RBC antigens when there is no alternative IVD

Non-molecular antisera laboratory developed tests (LDTs) for rare red blood cell (RBC) antigens when manufactured and performed by blood establishments, including transfusion services and immunohematology laboratories, and when there is no alternative in vitro diagnostic product (IVD) available to meet the patient's need for a compatible blood transfusion within the scope described in Section V.B.3 of the preamble to the Final LDT Rule (89 FR 37286).



Create Device Listing in FURLS/DRLM



Enter a Proprietary Name in this box, then click the Add Proprietary Name button below to add the name to this listing.

Proprietary Name

Check here if disclosure of this device proprietary (brand) name would reveal trade secret or confidential commercial information. Checking this box will prevent the name from appearing on the public FDA website.

Check here if the device is U.S goods returned or used equipment being imported into U.S.

Check here if t

Optional: Lab

This device is

Device Identifier

+ Add Proprietary Name

Facility: FDA, Silver Spring, Maryland, UNITED STATES

Products Listing

Listings Summary

- Review the listings in the "Added Listing(s)" table below.
- Make updates by selecting the appropriate icon. Select to edit listing, to remove listing, to view listing proprietary names.
- Select to add supporting document(s) to listing in preamendment status.
- Add more listings by clicking "Add New Product".

+ Add New Product

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities	Actions
New Listing	Enforcement Discretion		LRO	General surgery tray	Manufacturer	

< Go to Owner Operator List **Save & Exit** **Next >**

Review and Certify Registration



Review registration information and check box next to “Certification Statement”

Enter PIN/PCN numbers

Your owner/operator number will appear in the text of the Registration Confirmation message

The Official Correspondent (OC) will receive an email confirming that the establishment has been registered

Review and Certify Registration



By clicking the Submit button, I certify that the registration and listing information for this medical device facility, as shown on this page, is true. I understand that the submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C. 1001.

Enter Payment Confirmation Number

Facility: FDA, Silver Spring, Maryland, UNITED STATES

Enter your Payment Identification Number (PIN) and Payment Confirmation Number (PCN) for each registration shown below.

The PIN is an 8-digit number beginning with the number 5. The PCN is an 8-digit number beginning with the two character fiscal year - for 2025, the PCN begins with "25"

You must have a separate PCN for each registration shown. If you have not yet paid your annual registration user fee, you must visit the [FDA User Fee website](#) and pay for each registered facility prior to completing registration. If you have paid for your registration(s) and do not have your PIN and PCN, you can display your numbers by visiting the [FDA User Fee website](#)

Sample PIN - PCN: 50000000.24000000

Registration Number	Address
New registration being created	FDA, 10903 New Hampshire Ave, Silver Spring, Maryland, UNITED STATES

PIN	PCN
<input type="text"/>	<input type="text"/>

Submit >

< Previous

Submit >

Annual Registration Successful

Facility: SANCO, Rockville, Maryland, UNITED STATES

You have successfully updated your registration and listing information for 2017.

Your registration will be valid through December 31, 2017.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2017.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

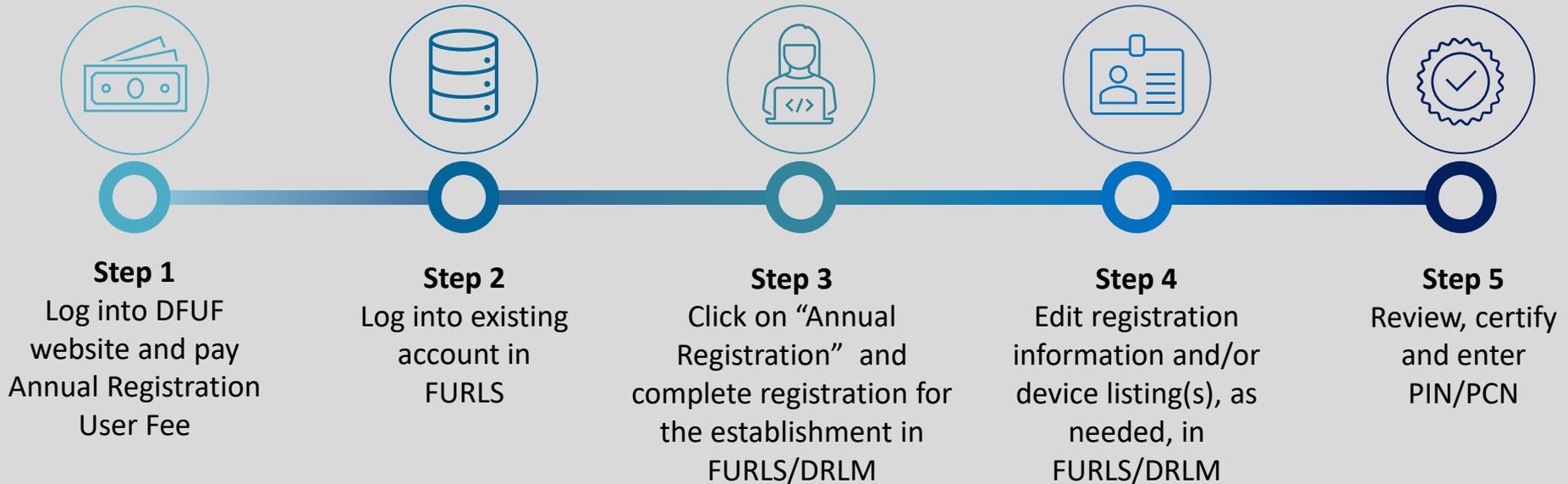
You may contact the FDA with any questions at reglist@cdrh.fda.gov.

The Owner/Operator Number for this Registration is: 10054564.

Establishment Registration and Device Listing



Steps for Annual Registration



DFUF: Device Facility User Fee Website
FURLS: FDA Unified Registration and Listing System
DRLM: Device Registration and Listing Module
PIN: Payment Identification Number
PCN: Payment Confirmation Number

Tutorial: www.fda.gov/media/107672/download



Pay the Annual Registration User Fee in DFUF Website



U.S. Department of Health & Human Services
FDA U.S. Food and Drug Administration
 Protecting and Promoting *Your* Health

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in the same FY will not be affected by this change in policy. If you have any questions regarding this change, please contact the User Fee Staff at userfees@fda.gov.

Log in to the User Fee System
[Login to Enterprise ICAM](#)

[Forgot User Name/Password?](#)
[New User? Please register...](#)

User Fee System Alerts

Please note the FDA's user fee credit card make an online payment with a credit card online payment option is still available for

Please note that you will only receive one for multiple facilities on the same order. The the quantity of facilities that you specified

Please note that the FURLS/DRLM account your facility) is separate from the user name (used for the Device Facility User Fee (DF regarding the registration process, please Helpdesk at regist@cdth.fda.gov or 301-

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FDA U.S. Food and Drug Administration
 Protecting and Promoting *Your* Health

User Fee Website
 Welcome FDA Test User

Annual Establishment Registration
 FY 2024 MDUFA Establishment Registration User Fee cover sheets should be created for payments associated with registrations for the period October 1st, 2023 through September 30th, 2024.

User Fee	Description	
MDUFA Establishment Registration User Fee 2024	FURLS Device Facility User Fee	Go

2024 Cover Sheets
 FY 2024 cover sheets should be created for payments associated with submissions to the FDA for the period October 1st, 2023 through September 30th, 2024.

User Fee	Description	
ANIMAL DRUG USER FEE 2024	ADUFA Pre-Market Cover Sheets	Go
ANIMAL GENERIC DRUG USER FEE 2024	AGDUFA Cover Sheets	Go
Biosimilar User Fee 2024	BsUFA Cover Sheets	Go
Generic Drug User Fee 2024	GDUFA Cover Sheets	Go
Medical Device User Fee 2024	MDUFA Cover Sheets (PMA, 510k, etc.)	Go
OTC Monograph User Fee 2024	OMUFA Cover Sheets (OMOR Only)	Go
Prescription Drug User Fee 2024	PDUFA Pre-Market Cover Sheets	Go



Log into Existing Account in FURLS

FDA Industry Systems

10/22/2024 There will be a full outage of the PNSI application for a deployment of PNSI version 15.0.0.

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.

I understand.

Login [Forgot Account ID](#) [Forgot Password](#)

U.S. Department of Health and Human Services

FDA | **ONLINE ACCOUNT ADMINISTRATION (OAA)**

Account Management

Account Management

- Edit Account Profile
- Change My Password
- Update System Access
- Create a Subaccount
- Deactivate a Subaccount
- Reactivate a Subaccount

Welcome to the FDA Industry Systems. You are logged in as fo

You may choose an option on the left to manage your account. To obtain access to available FDA systems, choose the **Update**

Registration and Listing Programs

Food

- Acidified/Low-Acid Canned Foods Registration and Process Filing
- Shell Egg Producer Registration

Medical Devices

- Device Registration and Listing Module

Export Certification and Tracking

- Biologics Export Certification Application and Tracking System (BECATS)





Click on Annual Registration to complete the annual registration for the Establishment in FURLS/DRLM



Review your registration and listing information



Make any necessary updates to establishment registration and/or device listing(s)

U.S. Department of Health and Human Services

FDA FURLS | **DRLM**
Device Registration & Listing Module

DRLM Home

Annual Registration ▾
Annual Registration

Facility Registration ▾
Register a New Medical Device Facility
Change Registration Information for a Facility
Cancel, Deactivate, or Reactivate a Facility Registration
View Your Registration and Listing Information

Important Notice: An establishment must visit the [FDA Us](#)
Who Must Pay: All establishments must pay the annual reg

Important Messages

NEW: The CDRH Learn Regulatory Overview of Device E
The FDA Reauthorization Act of 2017 (FDARA) was signe establishments.
The annual registration user fee is paid on a Fiscal Year



Review and Certify Registration



By clicking the Submit button, I certify that the registration and listing information for this medical device facility, as shown on this page, is true. I understand that the submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C. 1001.

Enter Payment Confirmation Number

Facility: FDA, Silver Spring, Maryland, UNITED STATES

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Sample PIN - PCN: 50000000.24000000

Registration Number	Address
New registration being created	FDA, 10903 New Hampshire Ave, Silver Spring, Maryland, UNITED STATES

PIN	PCN
<input type="text"/>	<input type="text"/>

Submit >

< Previous

Submit >

Annual Registration Successful

Facility: SANCO, Rockville, Maryland, UNITED STATES

You have successfully updated your registration and listing information for 2017.

Your registration will be valid through December 31, 2017.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2017.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

The Owner/Operator Number for this Registration is: 10054564.

Registration and Listing Help

For **questions regarding user fees**, please reach out to the User Fee Helpdesk, by e-mail at: userfees@fda.gov



For **general information about the registration and listing process** or assistance with entering your registration and listing information into FURLS/DRLM, please email the CDRH Registration and Listing Helpdesk at reglist@cdrh.fda.gov



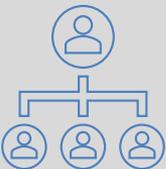
For **policy or specific questions about requirements for IVDs offered as LDTs**, please email the LDT Mailbox at LDTFinalRule@fda.hhs.gov



Registration and Listing Summary



Laboratories that manufacture IVDs, including laboratory developed tests, are generally required* to pay the annual registration user fee, and register and list the tests they manufacture



If a firm owns or operates more than one establishment, the firm can create the registration for each laboratory under their owner/operator account



Each IVD offered as an LDT must have its own device listing

*See preamble to the LDT final rule for targeted enforcement discretion policies

Next Webinar

Laboratory Developed Tests | FDA



Date

February 2025



Time

TBD



Topic

TBD

*Please submit questions in
advance to:*

CDRHWebinars@fda.hhs.gov

Resources and References

Slide Number	Resource	URL
4	Final Rule Regarding LDTs	www.federalregister.gov/public-inspection/2024-08935/medical-devices-laboratory-developed-tests
5,8	Code of Federal Regulations, Part 807	www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-807
7	Laboratory Developed Tests	www.fda.gov/medical-devices/in-vitro-diagnostics/laboratory-developed-tests
5,8	Code of Federal Regulations, Part 607	www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-607
5,8	Who Must Register, List and Pay the Fee	www.fda.gov/medical-devices/device-registration-and-listing/who-must-register-list-and-pay-fee
6	The OEI Development and Maintenance Procedure (SOP-000051)	www.fda.gov/media/137463/download
9	FURLS Device Registration & Listing Module for Initial Registration	www.accessdata.fda.gov/cdrh_docs/presentations/FURLS/story.html
10	CDRH LEARN: Paying the Annual Registration User Fee via the Device Facility User Fee (DFUF) Website	www.accessdata.fda.gov/cdrh_docs/presentations/AnnualFee/index.html

Resources and References

Slide Number	Resource	URL
11,12,13	DFUF	userfees.fda.gov/OA_HTML/furls.jsp
11,12,13	User Fee System (UFS) User Fee iStore Account Creation Desk Guide	https://userfees.fda.gov/OA_HTML/furls_account_creation.pdf
14	FURLS	www.access.fda.gov/oa/logonFlow.htm?execution=e1s1
14	FURLS Cover Sheet Creation: Step-by-Step Instructions	https://userfees.fda.gov/OA_HTML/FURLSCScreation.pdf
15	FDA Industry Systems Online Account	www.access.fda.gov/oa/logonFlow.htm?execution=e1s1
16-23	Register a New Medical Device Facility: Step-by-Step Instructions	www.access.fda.gov/drlm/help/RegisterANewMedicalDeviceFacility.html
16-23	FDA Industry Systems Account Management Guide	www.fda.gov/food/online-registration-food-facilities/fda-industry-systems-account-management-guide

Resources and References

Slide Number	Resource	URL
16-23	How to Register and List	www.fda.gov/medical-devices/device-registration-and-listing/how-register-and-list#initial
16-23	CDRH LEARN: Device Registration and Listing: An Introduction – Part 1	https://fda.yorkcast.com/webcast/Play/0d11c844da704628a6ea85b06b1dbe8b1d
16-23	CDRH LEARN: Device Registration and Listing: An Introduction – Part 2	https://fda.yorkcast.com/webcast/Play/764ece0cf29b47b48ac5c2e6cd765a0b1d
16-23	FURLS Device Registration and Listing Module for Annual Registration	www.fda.gov/media/107672/download
16-23	FURLS Device Registration and Listing Module for Initial Registration	www.accessdata.fda.gov/cdrh_docs/presentations/FURLS/story.html
16-23	DEVICE ADVICE: Device Registration and Listing	www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing
24-28	FURLS Device Registration & Listing Annual Registration	www.fda.gov/media/107672/download



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Previously Submitted Questions

Thanks for Joining Today!

- **Presentation and Transcript will be available at CDRH Learn**

- www.fda.gov/Training/CDRHLearn

- **Additional questions about today's webinar**

- Email: DICE@fda.hhs.gov

- **Upcoming Webinars**

- www.fda.gov/CDRHEvents



Start Here/The Basics! - <i>(Updated module 5/13/22)</i> <i>MDUFA Small Business Program, Registration and Listing</i>	▼
How to Study and Market Your Device - <i>(New module 12/23/21)</i> <i>510k, De Novo, IDE, PMA, HUD/HDE, Q-Submissions, Standards, Classification</i>	▼
Postmarket Activities - <i>(New modules 9/22/21)</i> <i>Quality System, Exporting, Device Recalls, MDR, Inspection - Global Harmonization</i>	▼
Unique Device Identification (UDI) System	▼
Specialty Technical Topics - <i>(Updated module 6/24/22)</i>	▼
Radiation-Emitting Products - <i>(Updated module 7/27/22)</i>	▼
510(k) Third Party Review Program (for Third Party Review Organizations)	▼
Industry Basics Workshop Series	▼



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