

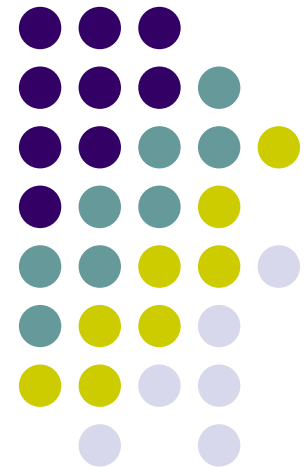


CDRH Registration and Listing Program

David Gartner

Regulatory Policy and Systems
Branch, Div. of Risk Mgt. Ops
Office of Compliance, CDRH

April 2010





Regulatory Authority

- Section 510 of the Food, Drug and Cosmetic Act As Amended requires establishment registration and device listing
- Regulation - 21 CFR Part 807, subparts A-D
 - A: Definitions
 - B: Procedures for Domestic Device Establishments
 - C: Registration Procedures for Foreign Device Establishments



Regulatory Authority

- Regulation - 21 CFR Part 807, subpart D, Exemptions (807.65)
 - Foreign
 - Raw materials, components
 - Veterinary purposes
 - General purpose articles
 - Carriers



Regulatory Authority

- Regulation - 21 CFR Part 807, subpart D, Exemptions (807.65)
 - Domestic
 - All noted under foreign
 - Practitioners
 - Pharmacies, surgical supply outlets, etc.
 - Research or teaching only
 - Persons who dispense to ultimate consumer



Regulatory Authority

- The Food and Drug Administration Amendments Act of 2007 (FDAAA) mandated use of electronic system and introduced annual registration user fee for many types of establishments, beginning October 1, 2007 for Fiscal Year 2008
- Changes to 21 CFR 807 will be published for comment in 2009

Electronic Registration and Listing



- FDA Unified Registration and Listing System (FURLS) Device Registration and Listing Module (DRLM) launched on October 1, 2007
 - Web-based entry of registration and listing information
 - Supports collection of Annual Registration User Fees

How Do I Register My Facility and List My Devices?



1. If you are required to pay the annual registration user fee, go to https://fdasfinapp8.fda.gov/OA_HTML/furls.jsp and purchase and pay the user fee for 2009
2. Once you have received confirmation of your payment or if you are not required to pay the fee, go to <https://www.access.fda.gov/oa/> and log into the electronic registration and listing system (FURLS).

How Do I Register My Facility and List My Devices?



3. Select Device Registration & Listing and select the appropriate choice from the menu

Do not select “Register a New Facility” if you have previously registered your facility. If you cannot find your previously registered facility, please contact the device registration and listing office at reglist@cdrh.fda.gov or 301-796-7400.



FURLS Accounts

- Account management is shared with other modules of the FDA Unified Registration and Listing System (FURLS)
 - DRFM – Drug Facility Registration
 - FFRM – Food Facility Registration
- On line help and tutorial available
- Owner may identify another party to be their official correspondent by creating a sub-account



FURLS Accounts

- Information entered into FURLS account management is automatically transferred to DRLM to identify the owner and official correspondent of an establishment
- Each owner should create and keep only one FURLS top level account
- Sub-accounts can be added to the top level accounts if new official correspondents need to be added



What Information Will I Need?

- If you have previously registered a facility using FURLS DRLM or - before October 2008 - by submitting a registration form:
 - You must have your FURLS Account ID and Password
 - If you do not have either your Account ID or Password, please do not create a new account

What Information Will I Need to Use FURLS DRLM?



- If you have your Account ID, but do not know your password, go to <https://www.access.fda.gov/oaa/resetPasswordQA.jsp> to reset your password.
- If you do not know your Account ID or have a problem resetting your password, please contact the device registration and listing office at reglist@cdrh.fda.gov or 301-796-7400.
- Do not create a new FURLS Account if you have ever registered a device facility with FDA

What Information Will I Need to Use FURLS DRLM?



- The owner's business name, address and contact information (including email address)
- The name, address and contact information (including email address) of the person who will be your official correspondent
 - Can be the same as your owner information
- Foreign only - the name, address and contact information (including email address) of your US agent

What Information Will I Need?



- The name and address of the establishment you are registering
- For devices that are exempt from premarket clearance or approval:
 - Product code for the device (can be identified during FURLS DRLM session)
 - What activity is performed at the establishment for the device (manufacture, relabel, etc.)
 - The proprietary or brand names that the device is marketed under (optional)

What Information Will I Need?



- For devices that require FDA clearance or approval:
 - The submission number from your clearance or approval letter (K123456, P123456, N12345, etc.)
 - The product codes, if any, that were shown on your clearance or approval letter
 - What activity is performed at the establishment for the device (manufacture, relabel, etc.)
 - The proprietary or brand names that the device is marketed under (optional)



What Information Will I Need?

- If your facility does any of the following you must pay the annual registration user fee and obtain a Payment Identification Number (PIN) and Payment Confirmation Number (PCN):
 - Manufacture
 - Manufacture and distribute for another party
 - Sterilize and distribute for another party
 - Reprocess single-use devices
 - Develop specifications for manufacture by another party

You will need your PIN and PCN to complete your registration



Registration Requirements

- Initial domestic establishment registration within 30 days of starting commercial distribution of a device
- Must create at least one listing/identify one product at time of initial registration
 - Initial distributors not required to submit listings at this time
- Annual registration required each year between October and December



Registration Requirements

- Registration is not complete and you will not be in compliance until:
 - You acknowledge the certification statement on the initial or annual registration summary page
 - At least one listing is entered (except for initial distributors)
 - If required, the user fee payment has been received by FDA

Foreign Establishment Requirements



- Prior to their devices being imported or offered for import to the United States, foreign establishments must:
 - Register their establishment
 - List their devices
 - Identify a United States agent
 - Pay the annual registration user fee, if required

Foreign Establishment Requirements – United States Agent



- All foreign establishments must:
 - Appoint a **single** United States agent and identify the agent separately to each Center
 - Notify FDA within 10 days of appointing or changing United States agent
- United States agent must reside or have a physical place of business in the United States - no Post Office boxes or mail drops allowed
- United States agent does not register

Foreign Establishments - U.S. Agent Responsibilities



- Assist FDA with scheduling of inspections
- Assist FDA with communications
- Accept information or documents that FDA is unable to provide directly to the foreign establishment
- Respond to questions concerning products being imported or offered for import
- May act as Official Correspondent if so designated by the foreign establishment
- US agent has no responsibility related to reporting adverse events or submitting 510(k) notifications



Device Listing Requirements

- Product Code Selection
 - Exempt Products – user may select correct product code from table displayed during DRLM listing process
 - Non-Exempt Products – the correct product codes are displayed by DRLM after the user enters the 510(k), PMA, NDA, HDE or PDP number
 - If the product codes displayed conflict with the codes on your equivalence letter, contact CDRH at reglist@cdrh.fda.gov

Device Listing Requirements – Exempt Devices



- One device listing for each type of device (not each model, catalog number, brand name) for products exempt from premarket clearance or approval
 - All exempt devices under one product code have only one listing
 - Although FURLS DRLM allows entry of multiple proprietary names, this information is not mandatory

Device Listing Requirements



- All foreign establishments, regardless of type, are required to list
- Domestic contract manufacturers and contract sterilizers who put the device in commercial distribution are required to list.
- Specification developers have to list even if they are using a foreign contract manufacturer or contract sterilizer



Device Listing Updates

- Annual review required between October and December during annual registration
 - Must acknowledge that the listings are complete and accurate even if no changes
 - Foreign establishments must list their devices prior to export to United States
- Updates are allowed throughout the year as new products are added or existing listings change



Viewing FURLS Data

- Each owner and official correspondent can view their up-to-date FURLS DRLM data by choosing “View Your Registration and Listing Information” from the DRLM main menu
- Publicly available device registration and listing information for all active registrants is available at <http://www.fda.gov/cdrh/comp/estregls.html>
 - The public database is only updated once a month



Annual Registration User Fees

- Congress has established a schedule of annual registration user fees for each fiscal year as shown below
 - FDA does not have the authority to waive or reduce the fee for anyone, including small businesses

Fiscal Year 2008	Fiscal Year 2009	Fiscal Year 2010	Fiscal Year 2011	Fiscal Year 2012
\$1,706	\$1,851	\$2,008	\$2,179	\$2,364

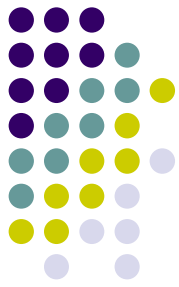
Independent Firms That Offer Registration and Listing Services



- Please be aware that various firms offer their services to assist both domestic and foreign establishments with registration and listing
- These firms are not affiliated with FDA and FDA has not contracted with any organization to register establishments or list their devices
- Any fees paid to these firms are not part of the annual registration user fees and the establishment must still pay the full amount to FDA (for FY09, \$1,851.00 US)

Accessing the User Fee Website

Device Facility User Fee



For questions, please contact the User Fee Helpdesk at (301) 827-9539 or userfees@fda.gov.

DEADLINE: FDA must receive all 2009 Establishment Registrations fees no later than December 30, 2008 for facilities to register by December 31, 2008. Please note the following restrictions:

- If paying by check or wire, allow 5 business days for FDA to receive your payment
- If paying online, allow 2 business days for FDA to receive your payment

To ensure that FDA processes your payment correctly, include the PIN (Payment Identification Number) on your check or wire transfer.

WIRE INFORMATION: FDA's wire information is now listed on the order form. Once you create your PIN and print out the submitted order, the wire information will show on the form.

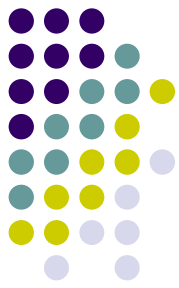
Due to the scheduled system maintenance, the User Fee Production System will not be available on Saturday, February 21st 9:00 AM to 5:00 PM.

☒ I am here for the first time to pay for my 2009 Establishment Registration Fee

☐ I am returning to the User Fee website to retrieve my PCN or create a new PIN

Sign into Device Facility User Fee (DFUF)

Create new Account



New Organization

* Indicates required field

Submit

Business Information

☒ United States Organization

☐ Foreign Organization

* Organization Name: DEMO CUSTOMER

* Organization Federal Employer Identification Number: 512695485

* Organization DUNS: 123456789

* Country: United States

* Address Line 1: 5600 Fishers Lane

Address Line 2:

Address Line 3:

Address Line 4:

* City: Rockville

County:

* State: MD

* Zip: 20857

Submit

New User Fee Account Creation



* Indicates required field

User Information

* First Name:	<input type="text" value="Tester"/>		
Middle Name:	<input type="text"/>		
* Last Name:	<input type="text" value="Testing"/>		
* Email Address:	<input type="text" value="test@democustomer.com"/>		
* Confirm Email Address:	<input type="text" value="test@democustomer.com"/>		
* Day Phone Number:	<input type="text" value="999"/>)	<input type="text" value="999-9999"/>	Ext. <input type="text"/>
Evening Phone Number:	<input type="text"/>)	<input type="text"/>	Ext. <input type="text"/>
Fax Number:	<input type="text"/>)	<input type="text"/>	Ext. <input type="text"/>
* User Name:	<input type="text" value="DEMOCUSTOMER"/>		
* Password:	<input type="password" value="••••••••"/>		
* Confirm Password:	<input type="password" value="••••••••"/>		

Your user name cannot contain any symbols. Your password must be at least 8 characters long but cannot repeat any of its characters or contain your user name. Your password must include the following character types: uppercase letters, lowercase letters, numbers, and one of the following symbols: @, #, \$, %, ^, &, *, !

FDA Use Only

User Fee Website Welcome Page



User Fee Website

Welcome Tester Testing

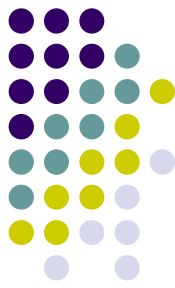
Annual Registration

User Fee	Description	
Establishment Registration User Fee 2009	FURLS Device Facility User Fee	Go

Cover Sheets

User Fee	Description	
Animal Drug User Fee 2009	ADUFA II Pre-Market Cover Sheets	Go
Medical Device User Fee 2009	MDUFMA Cover Sheets (PMA, 510k, etc.)	Go
Prescription Drug User Fee 2009	PDUFA Pre-Market Cover Sheets	Go

Device Facility User Fee – Order Creation



Device Facility User Fee

Device Facility User Fee

On October 1, 2008 FDA introduced an improved process for collecting device facility user fees and registrations. The new process includes 3 main steps:

1. **Sign up** (you are here)
2. **Pay**
3. **Register**

To read more about the new process, please [click here](#).

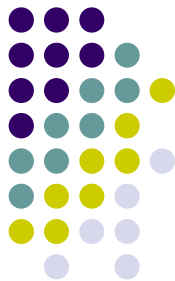
Begin step 1 by entering the number of facilities for which you are paying. For information about this step, please [click here](#).

You must complete the entire payment and registration process by December 31, 2008. Please provide enough time for payment processing, especially if you are paying by check.

Product	Quantity	Unit Price
Device Facility User Fee	<input type="text" value="1"/>	\$1,851.00 EACH

Add to Cart


Device Facility User Fee – Order Creation



Device Facility User Fee

Order

✓ Do not click the "Back" button in your browser to adjust your quantity. Instead change the number in the "Quantity" field and then click the "Recalculate" button.

Delete	Product	Quantity	Total Due
	Device Facility User Fee	<input type="text" value="1"/>	\$1,851.00
			<input type="button" value="Recalculate"/>

This order is in progress. Click the "Next" button to continue.

Device Facility User Fee – Address



Billing Information 1

Customer: DEMO CUSTOMER

Contact: Tester Testing
999-999-9999

Address:

Add / Edit Address

Next

Search and Select: Bill to Address 2

If you do not see the address you are looking for, please select the appropriate country from the list and click the "View All Contacts" button.

Search

Country: United States

Create Address

Results

View All Contacts

Select	Customer	Contact	Address	Primary	Address Type
<input checked="" type="radio"/>	DEMO CUSTOMER		5600 Fishers Lane Rockville,MD 20857 UNITED STATES		

Billing Information 3

Customer: DEMO CUSTOMER

Contact: Tester Testing
999-999-9999
marie.casseus@fda.hhs.g

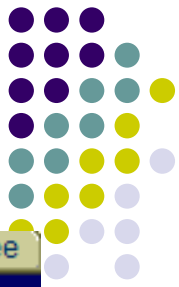
Address: 5600 Fishers Lane
Rockville,MD 20857
UNITED STATES

Add / Edit Address

Select

Next

Device Facility User Fee – Submit Order



Device Facility User Fee

Submit Order

Product	Quantity	Unit Price
Device Facility User Fee	1	\$1,851.00
		Total:\$1,851.00
Customer Information		
Customer: DEMO CUSTOMER Tester Testing 999-999-9999 marie.casseus@fda.hhs.gov		
Billing Information		
Bill To: Tester Testing DEMO CUSTOMER 5600 Fishers Lane Rockville,MD 20857 UNITED STATES		

Submit Order

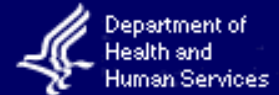
FDA Use Only



Device Facility User Fee – Confirmation



U.S. Food and Drug Administration



Thank you for completing step one of the payment process for your 2009 Establishment Registration Fee.

For your reference, your Payment Identification Number (PIN) is 50014736.

Now that you have received your PIN, you can proceed to make your payment. Once you make your payment, allow at least 2-3 business days for FDA to process online payments and wire transfers. It takes at least 7-10 business days for FDA to process paper checks from their postmark date.

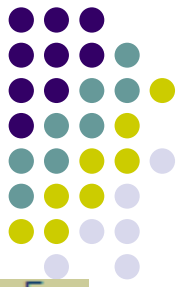
After your payment has been processed you will receive an email instructing you to retrieve your Payment Confirmation Number (PCN). You must retrieve your PCN to begin your facility registration.

Online Payments - Please Note: If you submit your payment online you will receive a tracking email, indicating that your payment has been submitted for processing. This email is not a payment confirmation; please allow 2-3 business days for the FDA to process your online payment. You will receive a second email from FDA once your PCN is available.

This information will be emailed to you as well.

Thank you,
FDA Office of Financial Management

Device Facility User Fee – Confirmation



Device Facility User Fee



Confirmation

Your order has been submitted electronically. Include your Payment Identification Number (PIN) with your payment.

Product	Quantity	Unit Price
Device Facility User Fee Print/View Final Order	1	\$1,851.00

Total:\$1,851.00

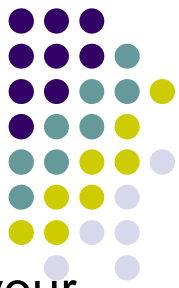
YOUR PAYMENT IDENTIFICATION NUMBER (PIN) IS:
50014736

[Pay Now](#)

[Create Another Order](#)

[What are my payment options?](#)

Device Facility User Fee – Pay.gov



System Message

- The system has populated the Payment Date with the next available payment date.

Online Payment [Return to your originating application](#)

Step 1: Enter Payment Information 1 | 2 | 3

This item is payable by [Bank Account Debit \(ACH\)](#) or [Plastic Card](#) (ex: VISA, Mastercard, American Express, Diners Club, Discover).

Option 1: Pay Via Bank Account (ACH) [about ACH Debit](#)

Required fields are indicated with a red asterisk *

Account Holder Name:

Payment Amount: \$1,851.00

Account Type:

Routing Number:

Account Number:

Confirm Account Number:

Check Number:

Routing Number: 026946763 Account Number: 9243767390 Check Number: 1234

Payment Date: 08/11/2008

Select the "Continue with ACH Payment" button to continue to the next step in the ACH Debit Payment Process.

[Continue with ACH Payment](#) [Cancel](#)

Note: Please avoid navigating the site using your browser's Back Button - this may lead to incomplete data being transmitted and pages being loaded incorrectly. Please use the links provided whenever possible.

Option 2: Pay Via Plastic Card (PC) (ex: VISA, Mastercard, American Express, Diners Club, Discover)

Required fields are indicated with a red asterisk *

Account Holder Name:

Payment Amount: \$1,851.00

Billing Address:

Billing Address 2:

City:

State / Province:

Zip / Postal Code:

Country: United States

Card Type:

Card Number:

Security Code:

Expiration Date:

Select the "Continue with Plastic Card Payment" button to continue to the next step in the Plastic Card Payment Process.

[Continue with Plastic Card Payment](#) [Cancel](#)

Note: Please avoid navigating the site using your browser's Back Button - this may lead to incomplete data being transmitted and pages being loaded incorrectly. Please use the links provided whenever possible.

1
(Electronic Check)

2
(Electronic Check)



1
(Credit Card)

2
(Credit Card)

- Step 1: Enter your credit card or electronic check information
- Step 2: Click on the appropriate confirmation button, either **Continue with ACH Payment** or **Continue with Plastic Card Payment**, depending on your selected payment method

Device Facility User Fee – Pay.gov



From:  paygovadmin@mail.qa.roc.bwai.gov
To: 
Cc:
Subject: Pay.Gov Payment Confirmation

← Confirmation Email

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Your transaction has been successfully completed.

Payment Summary

Application Name: FDA USER FEES
Pay.gov Tracking ID: 3FOCDIJO
Agency Tracking ID: 50000146

Account Holder Name: TEST DEVICE COMPANY
Transaction Type: Sale
Billing Address: 123 main st
Country: USA
Card Type: Master Card
Card Number: *****5100
Expiration Date: Jan, 2010
Payment Amount: \$1,851.00
Transaction Date: Aug 8, 2008 10:18:16 AM

Online Payment

Step 3: Confirm Payment

1 | 2 | 3

Thank you.
Your transaction has been successfully completed.
It is recommended you [print a copy](#) for your records.



[Print this window.](#)

Pay.gov Tracking Information

Application Name: FDA USER FEES
Pay.gov Tracking ID: 3FOCDIJO
Agency Tracking ID: 50000146

Transaction Date and Time: 08/08/2008 10:18 EDT

Payment Summary

Address Information

Account Holder TEST DEVICE
Name: COMPANY
Billing Address: 123 main st
Billing Address 2:
City:
State / Province:
Zip / Postal Code:
Country: USA

Account Information

Card Type: Master Card
Card Number: *****5100
Expiration Date: 1 / 2010

Payment Information

Payment Amount: \$1,851.00
Transaction Date 08/08/2008 10:18
and Time: EDT

Online Confirmation →

[Return to your agency website](#)

Device Facility User Fee – PCN



☐ I am here for the first time to pay for my 2009 Establishment Registration Fee

☒ I am returning to the User Fee website to retrieve my PCN or create a new PIN

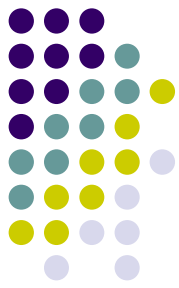
Attention:

The User Fee Website is different from the FURLS system. Your username and password for the User Fee website is different than your FURLS username and password. If you have not yet paid for your 2009 registration you will be required to create a new username and password for use on this website.

Sign into Device Facility User Fee (DFUF)

Returning user, please log in

Username	<input type="text" value="help1"/>
Password:	<input type="password" value="••••••••"/>
<input type="button" value="Sign into DFUF"/>	



Device Facility User Fee – PCN

User Fee Website

Welcome Tester Testing

Annual Registration

User Fee	Description	
Establishment Registration User Fee 2009	FURLS Device Facility User Fee	Go

Cover Sheets

User Fee	Description	
Animal Drug User Fee 2009	ADUFA II Pre-Market Cover Sheets	Go
Medical Device User Fee 2009	MDUFMA Cover Sheets (PMA, 510k, etc.)	Go
Prescription Drug User Fee 2009	PDUFA Pre-Market Cover Sheets	Go

Device Facility User Fee – PCN



[FAQ](#)



[UserFees](#)



[Order](#)



[Previous Orders / PCN](#)



[Profile](#)



[Logout](#)

Device Facility User Fee

Device Facility User Fee

On October 1, 2008 FDA introduced an improved process for collecting device facility user fees and registrations. The new process includes 3 main steps:

1. **Sign up** (you are here)
2. **Pay**
3. **Register**

To read more about the new process, please [click here](#).

Begin step 1 by entering the number of facilities for which you are paying. For information about this step, please [click here](#).



Device Facility User Fee – PCN

Track Orders

Track Orders

Below is a list of your orders. Click on the order number to view the order details. To search orders by dates, please use the calendar to enter them or type in dates in the format: 31-DEC-1999.

Orders in last:

Orders between: And

Search By: is

Results

<u>Order Number</u>	<u>Customer Name</u>	<u>Order Date</u>	<u>Order Status</u>	<u>Amount Owed</u>	<u>Action</u>
50014495	ENTRA HEALTH SYSTEMS	06-MAR-2009	Entered	\$1,851.00	Pay Now
50014494	ENTRA HEALTH SYSTEMS	06-MAR-2009	Booked	\$0.00	



Device Facility User Fee – PCN

US Department of Treasury
TREAS NYC
33 Liberty Street
New York, NY 10045

FDA Deposit Account Number: 75060099
Beneficiary: Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857
US Department of Treasury routing/transit number: 021030004
SWIFT Number: FRNYUS33

You must include the user fee payment identification number (PIN), and ensure that the fee that your bank will charge for the wire transfer is added to your fee payment.

2. Company Name and Address

ENTRA HEALTH SYSTEMS
338 Galloway Valley Ct.
Alpine CA 91901
US

2.1 Employer Identification Number (EIN)

830498402

3. Contact Name

entra health

3.1 E-mail Address

XX_eh@eh.com_FDA

3.2 Telephone Number

888-888888

3.3 Fax Number

4. PIN-PCN (Payment Identification Number-Payment Confirmation Number):

50014494-09117214

Registration and Listing Home Page



The screenshot shows a Windows Internet Explorer browser window displaying the US FDA/CDRH Registration & Listing home page. The browser's address bar shows the URL <http://www.fda.gov/cdrh/registpage.html>. The page features the FDA logo and the text "U.S. Food and Drug Administration" and "Department of Health and Human Services". Below this is the "CENTER FOR DEVICES AND RADIOLOGICAL HEALTH" and a navigation bar with links to "FDA Home Page", "CDRH Home Page", "Search", and "A-Z Index". A "Questions?" link is also present.

Registration & Listing

[Registration & Listing Home](#)

[Electronic Registration & Listing System \(FURLS\)](#)

[Who Must Register, List and Pay the Fee](#)

[When to Register & List](#)

[How to Register & List](#)

[Fees & Payments](#)

[Updating Information](#)

[Foreign Establishments](#)

[U.S. Agents](#)

[Documents](#)

[Search Registration & Listing](#)

[FDA > CDRH > Registration & Listing > Home](#)

Registration and Listing

[Subscribe to Email Updates](#)

Reminders:

- FDA is aware that various firms may be offering their services to assist domestic and/or foreign facilities to register with FDA. Please note that these firms are not affiliated with FDA, nor has the agency contracted with any firms to register facilities. **FDA does not use any outside contractors to notify or bill regulated industry about the need to register. FDA does not require firms to hire someone to complete the on-line registration process.**
- All device establishments must complete their annual registration for Fiscal Year 2009 between October 1, 2008 and December 31, 2008.
- FDA instituted on October 1, 2008 a new payment process for establishments that are required to pay the [device establishment user fee](#). If you are required to pay the establishment registration user fee (See [Who Must Register, List & Pay the Fee](#)), you must first visit the Device Facility User Fee website to pay the user fee. When logging onto the [Device Facility User Fee website](#), please create a new user name and password. Your registration user name and password from last year are only to be used in the electronic Registration and Listing System (FURLS) Once you make payment and receive confirmation for your payment, you can proceed to the FURLS website, using your user name and password from last year to

Local intranet 100%

FURLS Log-On and Account Creation Page



FDA Industry Systems - Accounts Management - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites

Address <https://www.access.fda.gov/oa/> Go Links

[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#)

FDA Industry Systems

[System Status](#) [Help Desk](#)

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.

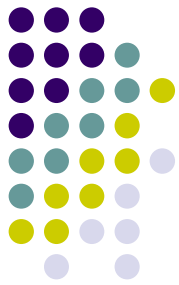
Is your computer secure? Before using FDA Industry Systems (FIS), FDA strongly encourages all users to have current antivirus and antispyware software installed on your computer to help ensure the privacy of the information being entered.

December 8, 2007 See [New features in PNSI version 1.9.00](#)


NEW USERS	LOGIN
Create New Account	Existing account holders, enter your account ID and password.
See Instructions	Account ID: <input type="text"/>
See Tutorials	Password: <input type="password"/> Forgot your password?
	<small>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.</small>

Local intranet

FURLS DRLM Menu












DRLM
Device Registration & Listing Module

 **FDA** FURLS HOME DRLM HOME

DRLM Main Menu

Get Help ?

-  [Annual Registration](#)
(Annual Review of Device Registration and Listing Information)
-  [View Your Registration and Listing Information](#)
-  [Change Registration Information for a Facility](#)
-  [Cancel, Deactivate, or Reactivate a Facility Registration](#)
-  [Change the Official Correspondent for a Facility](#)
-  [Register a **New** Medical Device Facility](#)
-  [Create Listings for Medical Devices](#)
-  [Change, Cancel, or Reactivate Listings](#)
-  [Transfer Ownership of Devices or Facilities](#)

Who Must Register, List, And Pay – Domestic Establishments



Activity	Register	List	Pay Fee
Manufacturer	Yes	Yes	Yes
Manufactures a custom device	Yes	Yes	Yes
Manufacturer of accessories or components that are packaged or labeled for commercial distribution for health-related purposes to an end user	Yes	Yes	Yes
Manufacturer of components that are distributed only to a finished device manufacturer	No	No	No
U.S. Manufacturer of export only devices	Yes	Yes	Yes
Relabeler or Repackager	Yes	Yes	No
Contract manufacturer who commercially distributes the device for the specifications developer	Yes	Yes	Yes
Contract manufacturer who does NOT commercially distribute the device for the specifications developer	No	No	No
Contract manufacturer of subassembly or component, Contract Packager or Labeler	No	No	No

Who Must Register, List, And Pay – Domestic Establishments – Cont.



Activity	Register	List	Pay Fee
Contract sterilizer who commercially distributes the device	Yes	Yes	Yes
Contract sterilizer who does NOT commercially distribute the device	No	No	No
Kit Assembler	Yes	Yes	Yes
Domestic Distributor	No	No	No
Specification Developer	Yes	Yes	Yes
Specification Consultant Only	No	No	No
Initial Distributor/Importer	Yes	No	No
Device being investigated under IDE	No	No	No
Reprocessor of single-use devices	Yes	Yes	Yes
Remanufacturer	Yes	Yes	No

Who Must Register, List, And Pay – Foreign Establishments



Activity	Register	List	Pay Fee
Manufacturer	Yes	Yes	Yes
Manufactures a custom device	Yes	Yes	Yes
Exports Product to United States, Performs No Other Operation	Yes	Yes	No
Relabeler or Repackager	Yes	Yes	No
Contract manufacturer	Yes	Yes	Yes
Contract sterilizer	Yes	Yes	Yes
Kit Assembler	Yes	Yes	Yes
Specification Developer	Yes	Yes	Yes
Device being investigated under IDE	No	No	No
Reprocessor of single-use devices	Yes	Yes	Yes
Remanufacturer	Yes	Yes	No

Sources of Registration and Listing Information



1. Registration and Listing and FURLS Information
<http://www.fda.gov/cdrh/reglistpage.html>
2. Establishment Registration (part of Device Advice)
<http://www.fda.gov/cdrh/devadvice/341.html>
3. Medical Device Listing (part of Device Advice)
<http://www.fda.gov/cdrh/devadvice/342.html>

Sources of Registration and Listing Information



4. Releasable Establishment Registration and Device Listing Files for download (will become available in June 2008) -
<http://www.fda.gov/cdrh/comp/estregls.html>
5. Searchable Public Database -
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>
6. Product Code Classification Database
<http://www.fda.gov/cdrh/prodcode.html>

How to Contact R&L Program Office



- E-mail is best method for contacting us:
 - E-mail for help with FURLS DRLM is reglist@cdrh.fda.gov
 - E-mail for policy questions and import detention issues: device.reg@fda.hhs.gov
- Phone number:
 - 301-796-7400

Definitions – Establishment Types/Activities



- **Initial Importer (Initial Distributor)** - Any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes the final delivery or sale of the device to the ultimate consumer or user, but who is not the specification developer and does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package.

Definitions – Establishment Types/Activities



- **Manufacturer** - Makes by chemical, physical, biological, or other procedures, any article that meets the definition of "device" in section 201(h) of the Federal Food, Drug, and Cosmetic (FD&C) Act.
- **Foreign Exporter** - Exports or offers for export to the United States, a device manufactured or processed by another person in a foreign country.

Definitions – Establishment Types/Activities



- **Contract Manufacturer** - Manufactures a finished device to another establishment's specifications and puts the device in commercial distribution for the other establishment.
- **Contract Sterilizer** - Provides a sterilization service for another establishment's devices and puts the device into commercial distribution.

Note: *By exporting their device(s) to the United States, all foreign contract manufacturers and sterilizers are putting the device into commercial distribution and, therefore, must register, list and pay the annual registration fee.*

Definitions – Establishment Types/Activities



- **Specification Developer** - Develops specifications for a device that is distributed under the establishment's own name but performs no manufacturing operations on the device. This also includes establishments that arrange for the manufacturing of devices labeled with another establishment's name.

Definitions – Establishment Types/Activities



- **Repackager** - Packages finished devices from bulk or repackages devices made for the establishment by a manufacturer into different containers (excluding shipping containers).
- **Relabeler** - Changes the content of the labeling from that supplied from the original manufacturer for distribution under the establishment's own name. A relabeler does not include establishments that do not change the original labeling but merely add their own name.

Definitions – Establishment Types/Activities



- **Remanufacturer** - Processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance, safety specifications, or intended use.
- **Single Use Reprocessor** - Performs remanufacturing operations on a single use device.
- **U.S. Manufacturer of Export-Only Devices** – Manufactures device for export to foreign countries that is not on the market in the U.S. (see www.fda.gov/cdrh/devadvice/39.html)



Other Definitions

- **Device Listing Number** - A seven-digit alphanumeric that is assigned to identify a product listing in FURLS DRLM that is unique to a product and an owner/operator.
- **Registration number** - A unique one- to ten-digit number assigned to identify an establishment
- **Owner/Operator Number** - A unique seven or eight-digit number assigned by CDRH to each owner/operator. The owner/operator is the entity or person who owns or oversees the operation of the registered establishment.



Definitions

- Submission Number – the premarket clearance or approval number assigned to a product by FDA. This includes:

Submission Number	Format
Premarket Approval (PMA)	P123456 or BP123456
Premarket Notification (510(k))	K123456 or BK123456
New Drug Application (NDA)	N12345
Humanitarian Device Exemption (HDE)	H123456
Product Development Protocol (PDP)	D123456

Note: To list devices marketed prior to the Medical Device Amendments of 1976 in FURLS DRLM, you must enter the word “Preamendment” in the field where the submission number would normally be entered.