CDRH Registration and Listing Program

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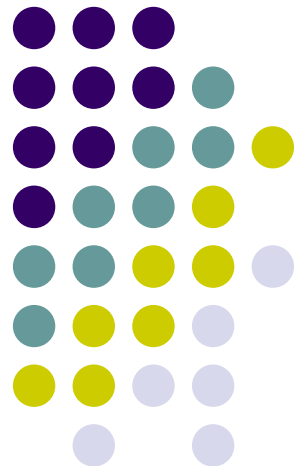
Office of Compliance, CDRH

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

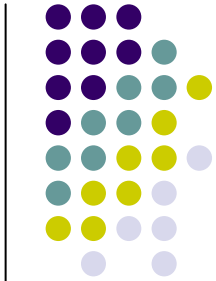
Regulatory Authority

- 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

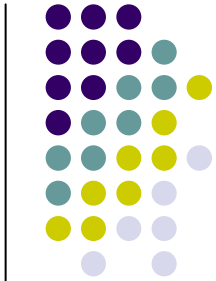
- The Food and Drug Administration Amendments Act of 2007 (FDAAA) mandated use of electronic system and introduced annual registration user fee for many types of establishments, beginning October 1, 2007 for Fiscal Year 2008
- Changes to 21 CFR 807 will be published for comment in 2009

Electronic Registration and Listing



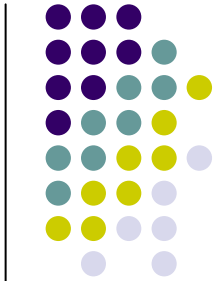
- FDA Unified Registration and Listing System (FURLS) Device Registration and Listing Module (DRLM) launched on October 1, 2007
  - Web-based entry of registration and listing information
  - Supports collection of Annual Registration User Fees

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/oaa/ and log into the electronic registration and listing system (FURLS).

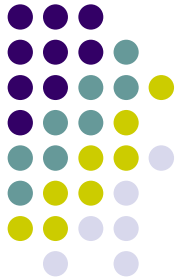
How Do I Register My Facility and List My Devices?



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:
  - Your 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

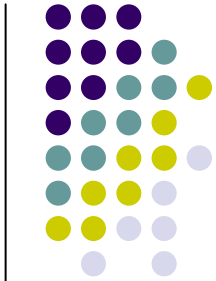
What Information Will I Need to Use FURLS DRLM?

- 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?

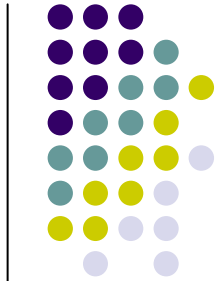
- If your facility does any of the following you must pay the annual registration user fee and obtain a Payment Identification Number (PIN) and Payment Confirmation Number (PCN):
  - Manufacture
  - Manufacture and distribute for another party
  - Sterilize and distribute for another party
  - Reprocess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

You will need your PIN and PCN to complete your registration

Registration Requirements

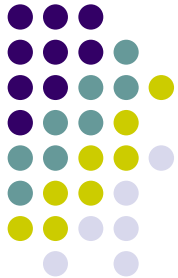
- Initial domestic establishment registration within 30 days of starting commercial distribution of a device
- Must create at least one listing/identify one product at time of initial registration
  - Initial distributors not required to submit listings at this time
- Annual registration required each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

Registration Requirements



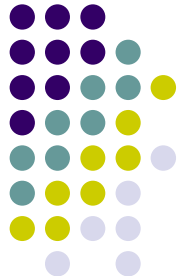
- Registration is not complete and you will not be in compliance until:
  - You acknowledge the certification statement on the initial or annual registration summary page
  - At least one listing is entered (except for initial distributors)
  - If required, the user fee payment has been received by FDA

Foreign Establishment Requirements



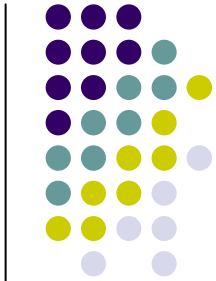
- Prior to their devices being imported or offered for import to the United States, foreign establishments must:
  - Register their establishment
  - List their devices
  - Identify a United States agent
  - Pay the annual registration user fee, if required

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

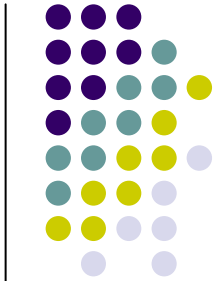
Device Listing Requirements

- 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

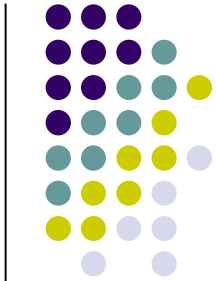
- One device listing for each type of device (not each model, catalog number, brand name) for products exempt from premarket clearance or approval
  - All exempt devices under one product code have only one listing
  - Although FURLS DRLM allows entry of multiple proprietary names, this information is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

Device Listing Requirements



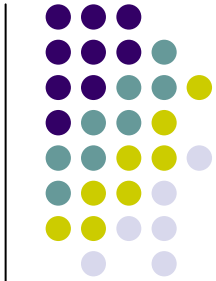
- All foreign establishments, regardless of type, are required to list
- Domestic contract manufacturers and contract sterilizers who put the device in commercial distribution are required to list.
- Specification developers have to list even if they are using a foreign contract manufacturer or contract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

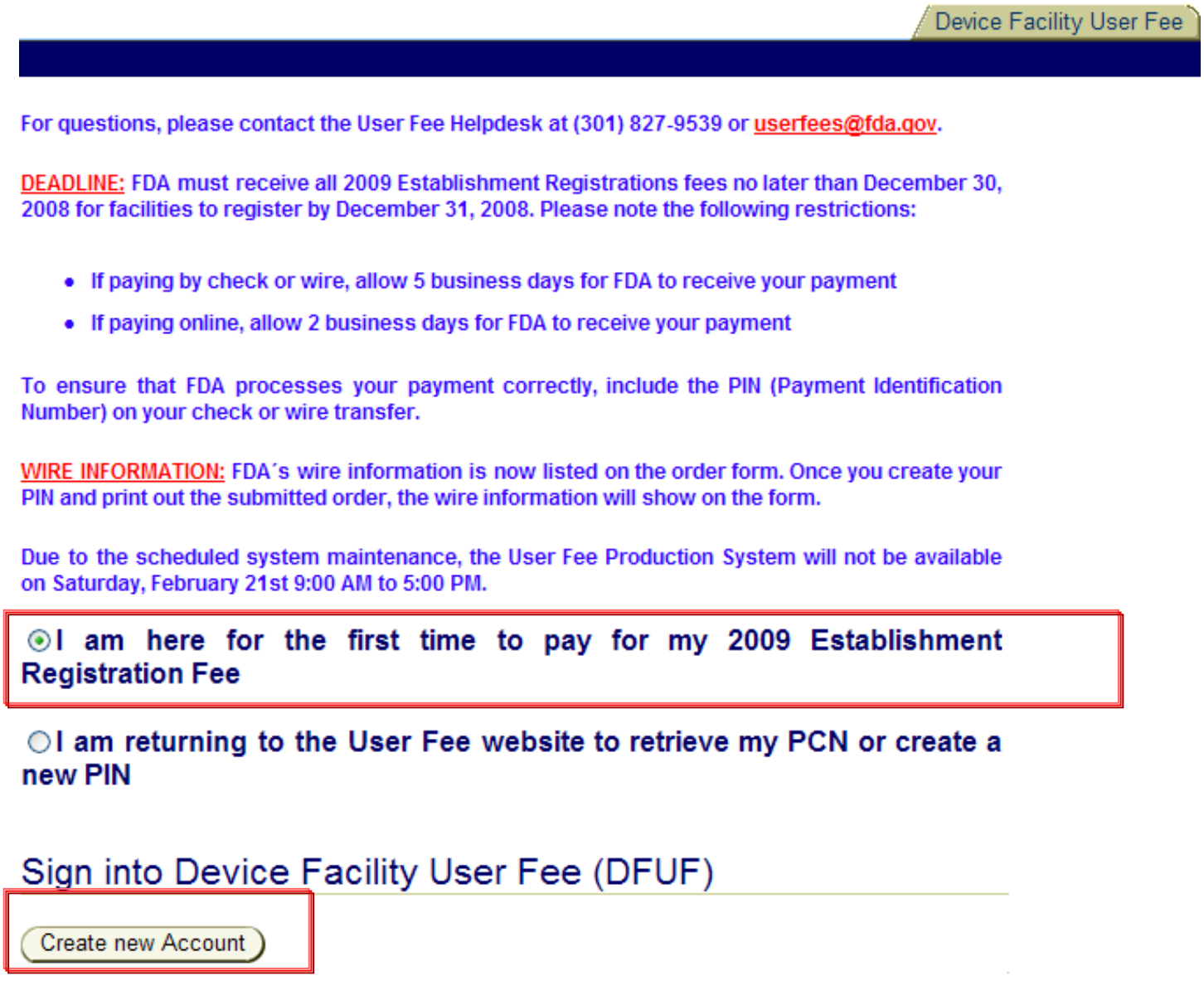
- Congress has established a schedule of annual registration user fees for each fiscal year as shown below
  - FDA does not have the authority to waive or reduce the fee for anyone, including small businesses

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



New Organization

* Indicates required field

Submit

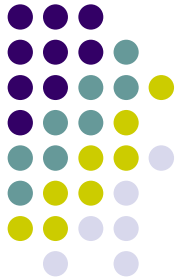
Business Information

- (•) 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:	Tester
Middle Name:	
* Last Name:	Testing
* Email Address:	test@democustomer.com
* Confirm Email Address:	test@democustomer.com
* Day Phone Number:	(999) 999-9999 Ext.
Evening Phone Number:	( ) Ext.
Fax Number:	( ) Ext.
* User Name:	DEMOCUSTOMER
* Password:	••••••••••••
* Confirm Password:	••••••••••••

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: @, #, $, %, ^, &, *, !

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

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.

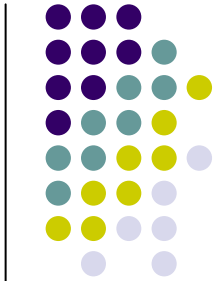
Begin step 1 by entering the number of facilities for which you are paying. For information about this step, please click here.

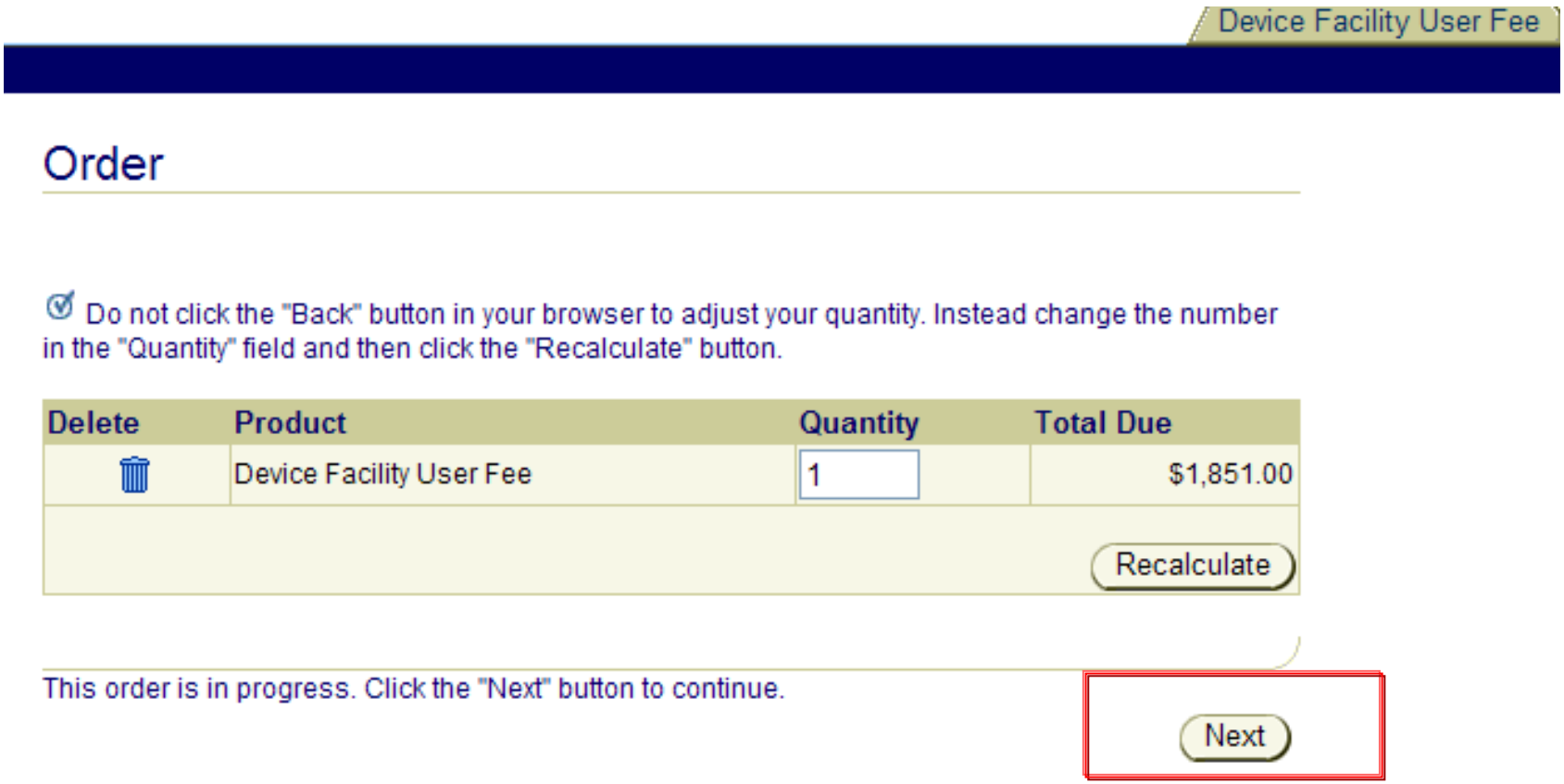
You must complete the entire payment and registration process by December 31, 2008. Please provide enough time for payment processing, especially if you are paying by check.

Product	Quantity	Unit Price
Device Facility User Fee	1	$1,851.00 EACH

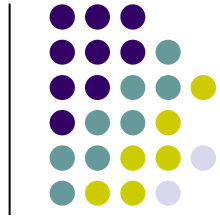
Add to Cart

Device Facility User Fee – Order Creation





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
◉	DEMO CUSTOMER		5600 Fishers Lane Rockville,MD 20857 UNITED STATES		

Select

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

Next

Device Facility User Fee – Submit Order

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

Device Facility User Fee – Confirmation

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.

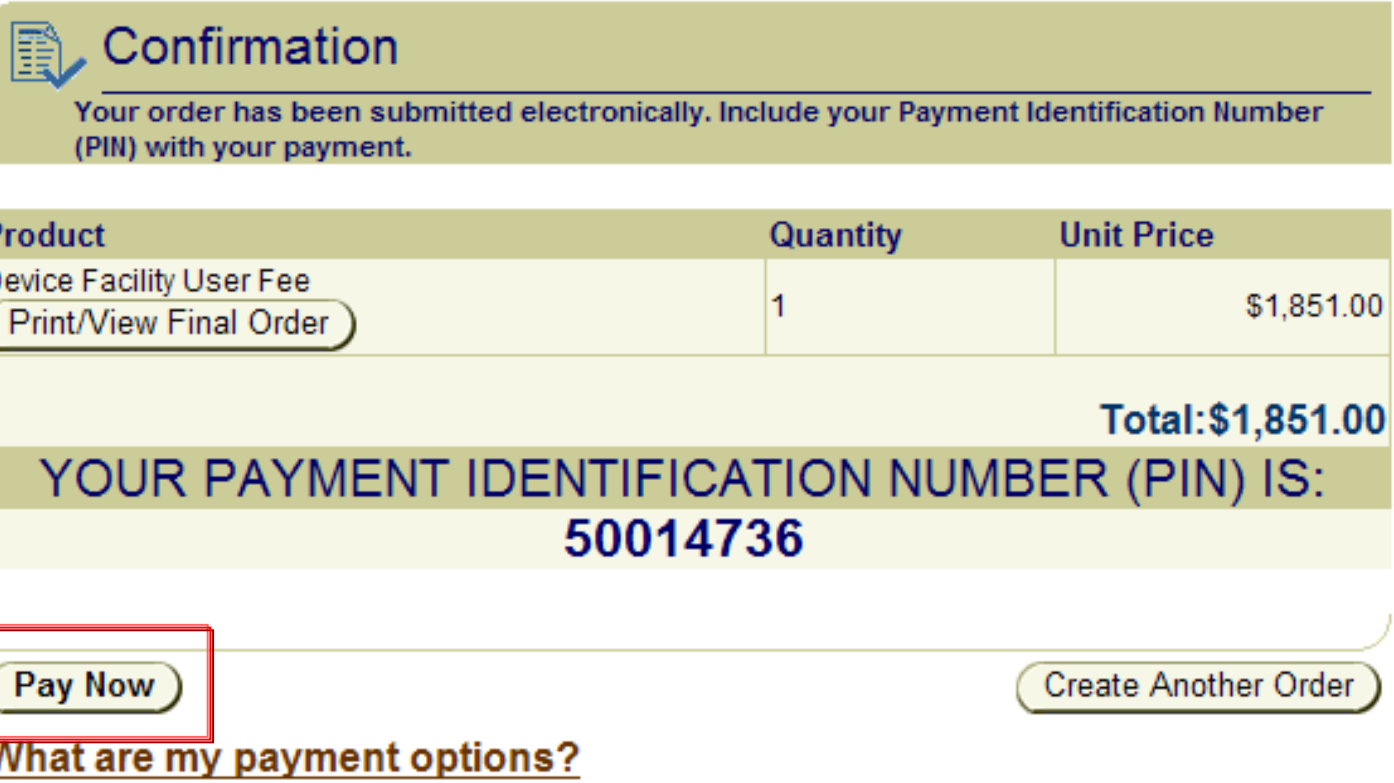
After your payment has been processed you will receive an email instructing you to retrieve your Payment Confirmation Number (PCN). You must retrieve your PCN to begin your facility registration.

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.

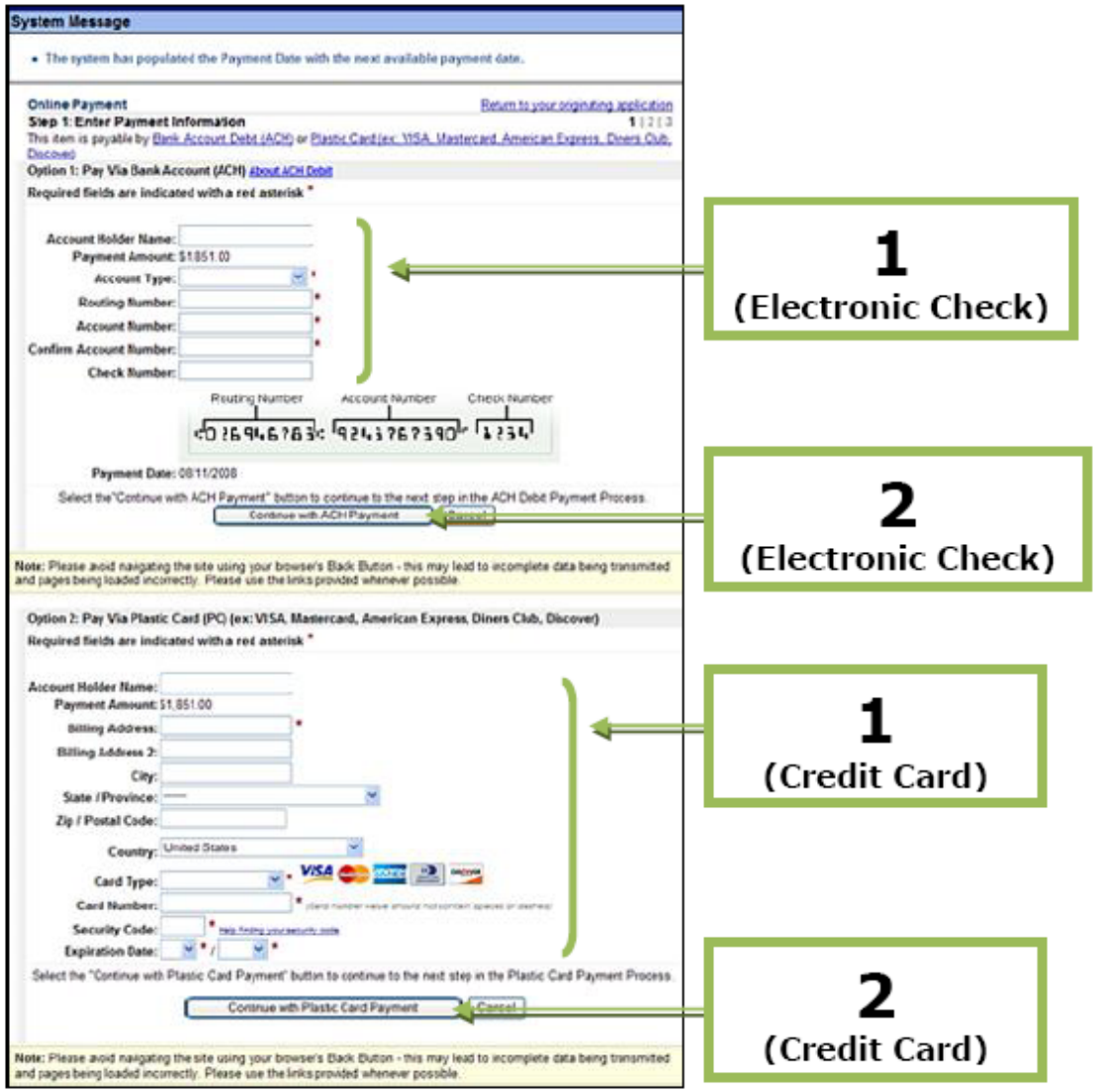
This information will be emailed to you as well.

Thank you,
FDA Office of Financial Management

Device Facility User Fee – Confirmation



Device Facility User Fee – Pay.gov



- *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

Confirmation Email

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

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 Confirmation

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 Information	Payment Information
Account Holder Name: TEST DEVICE COMPANY	**Card Type:** Master Card	**Payment Amount:** $1,851.00
Billing Address: 123 main st	**Card Number:** **********5100	**Transaction Date and Time:** 08/08/2008 10:18 EDT
Billing Address 2:	**Expiration Date:** 1 / 2010	
City:		
State / Province:		
Zip / Postal Code:		
Country: USA		

Return to your agency website

Device Facility User Fee – PCN

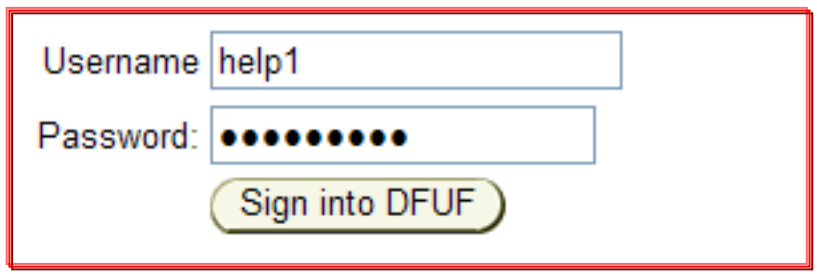
○ I am here for the first time to pay for my 2009 Establishment Registration Fee

◉ 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



Device Facility User Fee – PCN

User Fee Website

Welcome Tester Testing

Annual Registration

User Fee	Description	
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Device Facility User Fee – PCN

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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: 7 days Go

Orders between: And Go

Search By: Order Number is Go

Results

Order Number	Customer Name	Order Date	Order Status	Amount Owed	Action
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

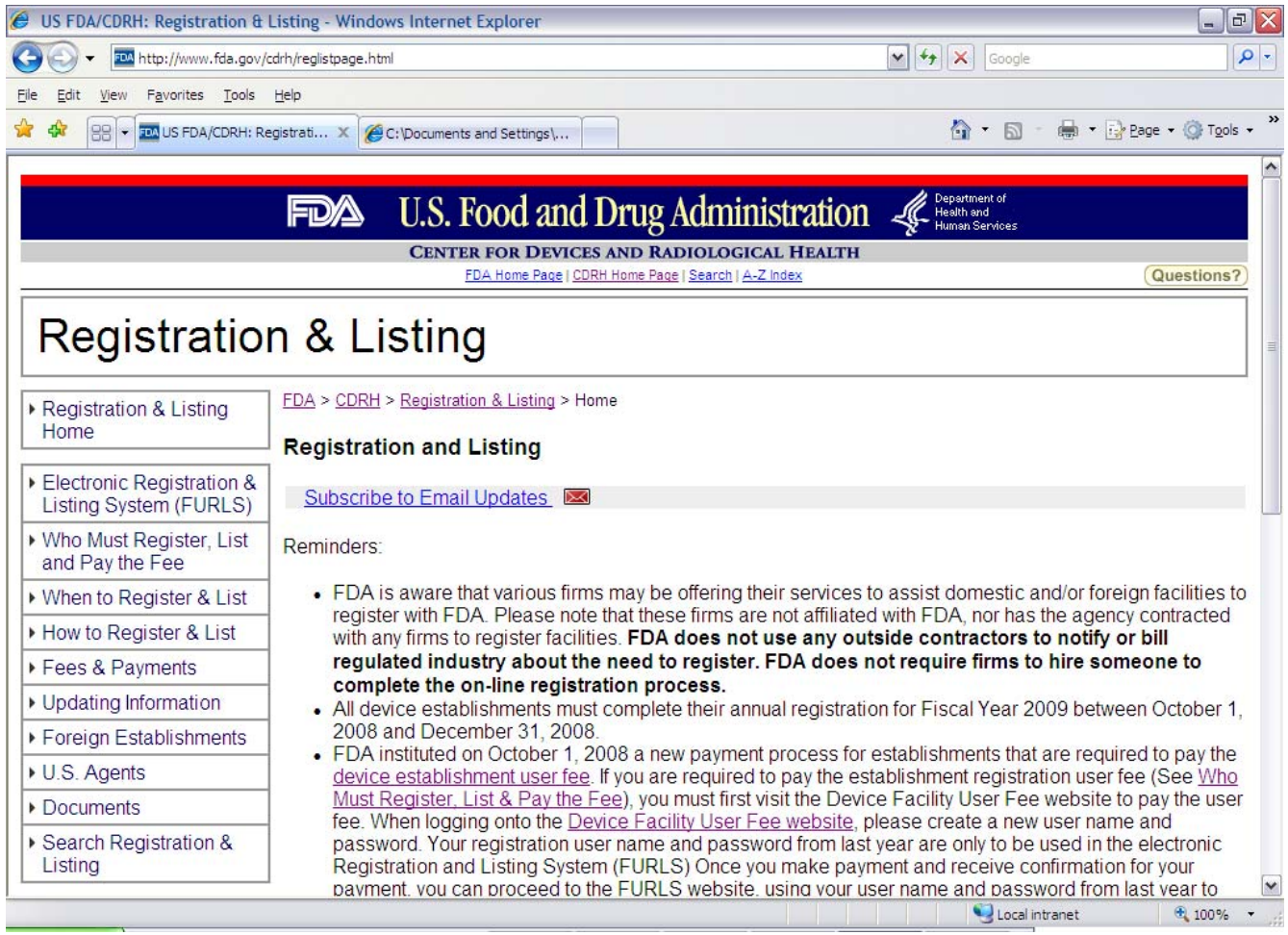
You must include the user fee payment identification number (PIN), and ensure that the fee that your bank will charge for the wire transfer is added to your fee payment.

2. Company Name and Address	3. Contact Name
ENTRA HEALTH SYSTEMS 338 Galloway Valley Ct. Alpine CA 91901 US	entra health
2.1 Employer Identification Number (EIN)	3.1 E-mail Address
830498402	XX_eh@eh.com_FDA
	3.2 Telephone Number
	888-888888
	3.3 Fax Number

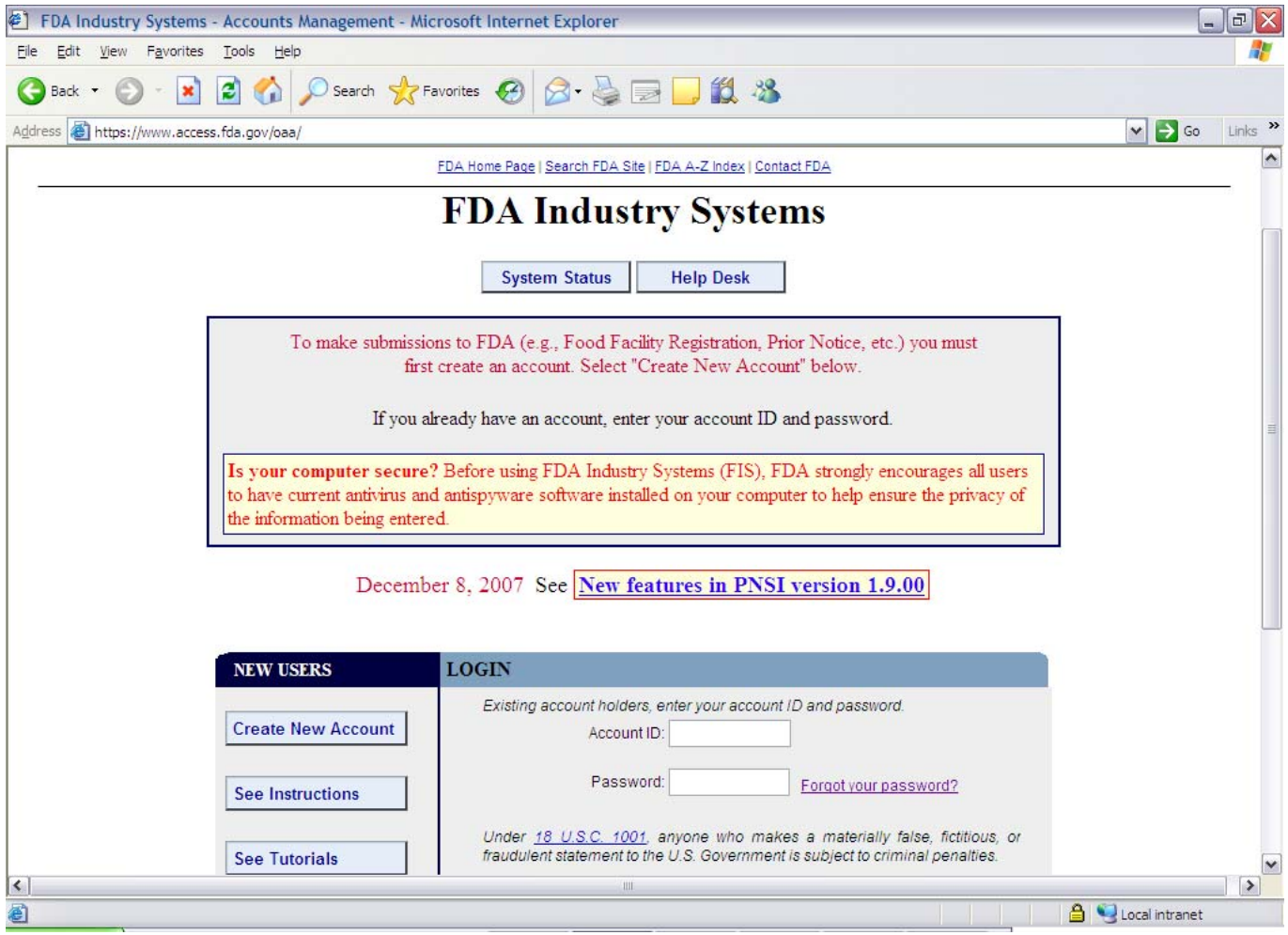
4. PIN-PCN (*Payment Identification Number-Payment Confirmation Number*):

50014494-09117214

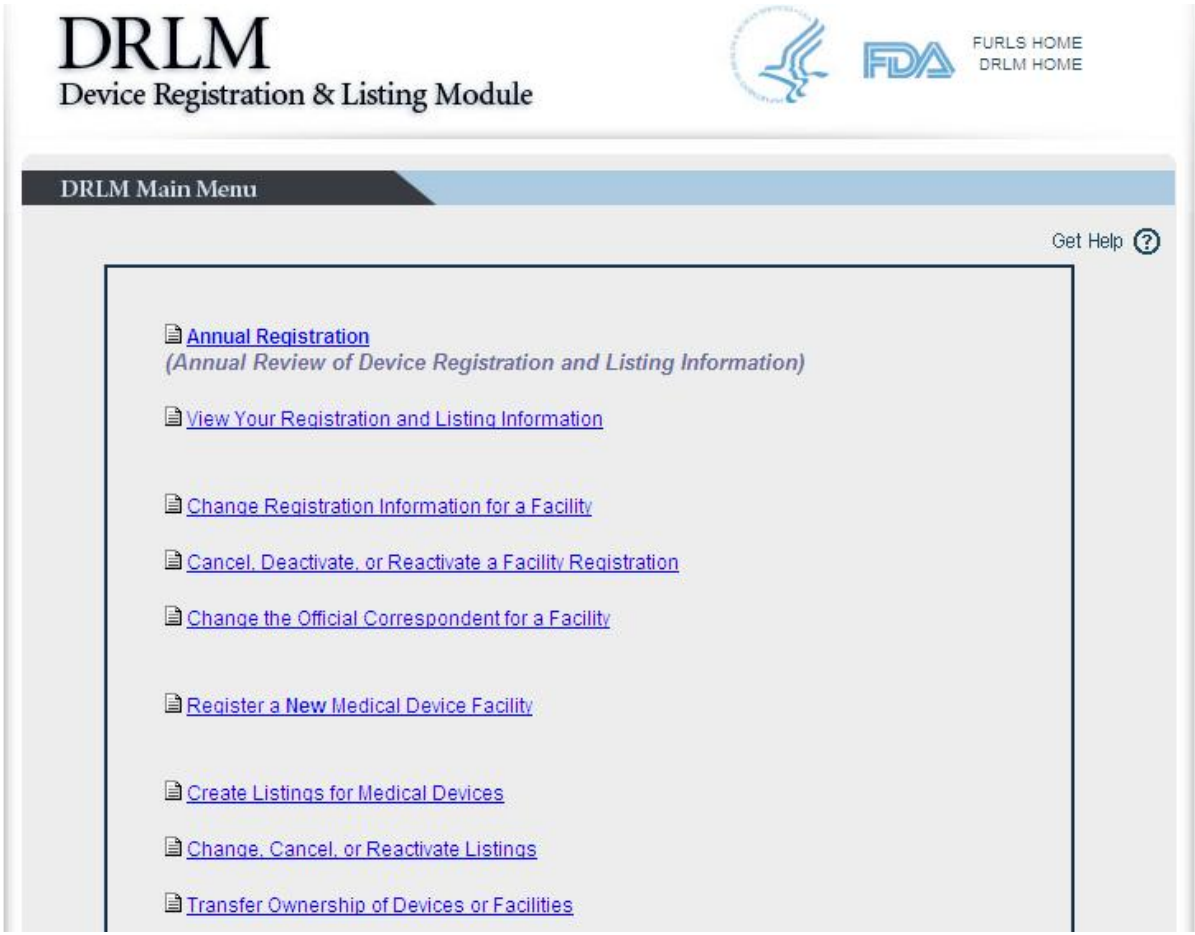
Registration and Listing Home Page



FURLS Log-On and Account Creation Page



FURLS DRLM Menu



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

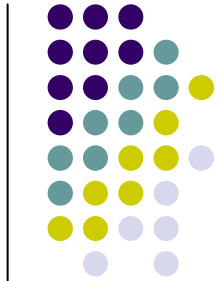
Sources of Registration and Listing Information

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

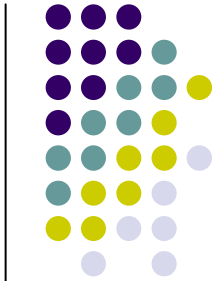
- E-mail is best method for contacting us:
  - E-mail for help with FURLS DRLM is reglist@cdrh.fda.gov
  - E-mail for policy questions and import detention issues: device.reg@fda.hhs.gov
- Phone number:
  - 301-796-7400

Definitions – Establishment Types/Activities



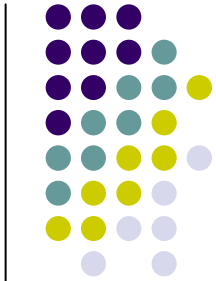
- **Initial Importer (Initial Distributor)** - Any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes the final delivery or sale of the device to the ultimate consumer or user, but who is not the specification developer and does not repackage, or otherwise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

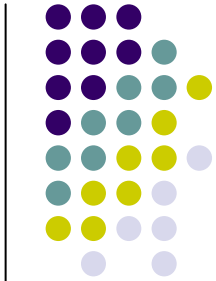
Definitions – Establishment Types/Activities



- **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.

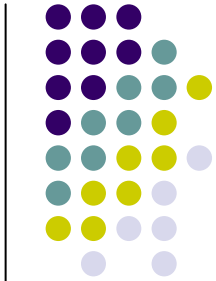
Note: *By exporting their device(s) to the United States, all foreign contract manufacturers and sterilizers are putting the device into commercial distribution and, therefore, must register, list and pay the annual registration fee.*

Definitions – Establishment Types/Activities



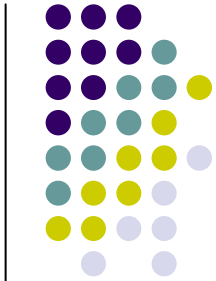
- **Specification Developer** - Develops specifications for a device that is distributed under the establishment's own name but performs no manufacturing operations on the device. This also includes establishments that arrange for the manufacturing of devices labeled with another establishment's name.

Definitions – Establishment Types/Activities



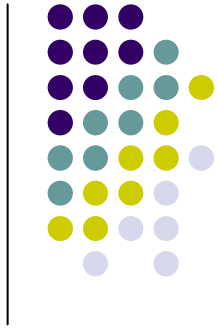
- **Repackager** - Packages finished devices from bulk or repackages devices made for the establishment by a manufacturer into different containers (excluding shipping containers).
- **Relabeler** - Changes the content of the labeling from that supplied from the original manufacturer for distribution 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.