

Paying the Annual Registration User Fee via the Device Facility User Fee (DFUF) Website

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

Division of Industry and Consumer Education (DICE)

Narrative: Welcome to Paying the Annual Registration User Fee via the Device Facility User Fee (DFUF) Website tutorial. This tutorial provides a brief introduction, login instructions for the DFUF Website, and instructions for paying the annual registration user fee. If during this tutorial you need assistance with the instructions, click on Resources on the left menu for Helpdesk information.

Annual Registration User Fee Introduction

- All medical device establishments are required to register and pay the annual registration user fee.
- Anticipated fees for the current and upcoming Fiscal Years are posted on the Device Registration and Listing page.
- The annual registration fee must be paid before completing your annual registration or before making changes in the FDA Unified Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM).
- One payment per year for each establishment (not per company or per product).

Narrative: You are required to register and pay the annual registration user fee for each medical device establishment each year. To access the anticipated fees for Fiscal Years 2013 - 2017, click on the link to the Medical Device Website. The fee must be paid for the current fiscal year before you can complete your annual registration or make any changes in the FDA Unified Registration and Listing System (FURLS)/Device Registration and Listing Module.

DFUF Login Instructions

1. To begin, open [How to Register and List](#) and click Paying the Annual Registration Fee.
2. Click on the Device Facility User Fee (DFUF) website link.
3. In DFUF, review the statement and click the radial button next to I understand.
4. Enter your DFUF username and password to log into DFUF (DFUF and FURLS/DRLM logins are different). If you are a new user, click on New User and follow the prompts to create a new account. Click Login.
5. On the New User Registration page, select an option and fill in the corresponding text box. Then, click Go.
6. Under Annual Establishment Registration, click Go on the “MDUFA Establishment Registration User Fee” line to open the Device Facility User Fee page.
7. On the Device Facility User Fee Page, enter the number of establishments and click Add to Cart.
8. On the Order page, ensure your quantity is correct. (Click Recalculate if you need to change the quantity.) Then, click Next.
9. Review billing information (add or edit address if needed) and click Next.
10. Review the order and click Submit Order to receive your PIN.
11. Click Close Window to open Confirmation page.
12. On the Confirmation page, click Pay Now to pay via credit card, electronic check, wire transfer, or to mail a check. Click on Payment Options on left menu for more information. After your payment is processed, you will receive your PCN.

Step 1

1. To begin, open the [How to Register and List](https://www.fda.gov/medical-devices/device-registration-and-listing/how-register-and-list) page and click **Paying the Annual Registration Fee**.



[How to Register and List](https://www.fda.gov/medical-devices/device-registration-and-listing/how-register-and-list)

Narrative: For best results, review these instructions with the DFUF Website open in another browser window.

Step 2

2. Click on the Device Facility User Fee (DFUF) Website link.

Paying the Annual Registration Fee

You may pay the annual registration fee electronically at the [Device Facility User Fee \(DFUF\) website](#).

You will receive your Payment Identification Number (PIN) when you make your payment on the DFUF site. You will receive notification of payment confirmation and instructions on obtaining your Payment Confirmation Number (PCN) by email once your payment has cleared. This process can take several days, so be sure to make payment at least a few days before registering.

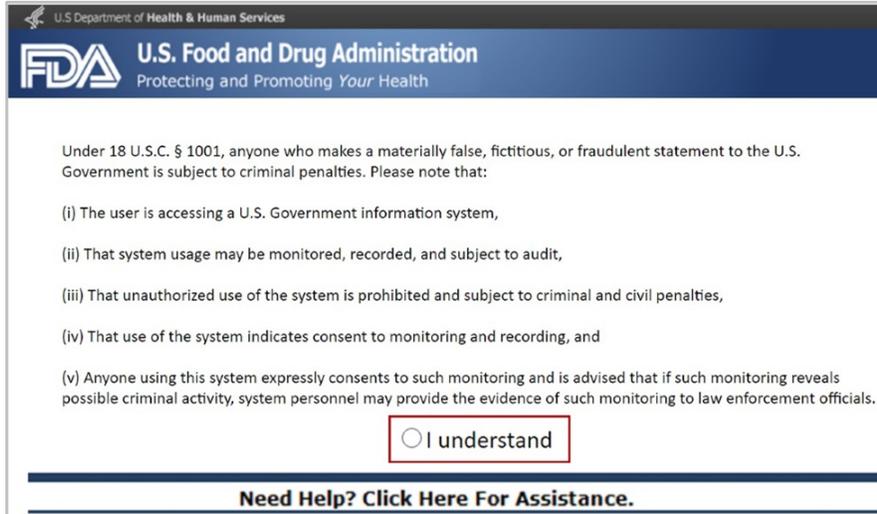
For additional information, please see [Payment Process](#).

Once you have received confirmation of your payment, you can proceed with registering your facility.

Narrative: Under the paragraph titled Paying the Annual Registration Fee, click the Device Facility User Fee (DFUF) Website.

Step 3

3. In DFUF, review the statement and click the radial button next to **I understand**.



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

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. Please note that:

- (i) The user is accessing a U.S. Government information system,
- (ii) That system usage may be monitored, recorded, and subject to audit,
- (iii) That unauthorized use of the system is prohibited and subject to criminal and civil penalties,
- (iv) That use of the system indicates consent to monitoring and recording, and
- (v) Anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.

I understand

Need Help? Click Here For Assistance.

Narrative: Review the statement and click "I understand" to open the DFUF Log-in page.

Step 4

4. Enter your DFUF username and password to log into DFUF. If you are a new user, click on New User and follow the prompts to create a new account.

Note: The DFUF and FURLS/DRLM login is different.



Log in to the User Fee System

User Name: Password:

[Forgot User Name/Password?](#)

[New User? Please create a User Fee account.](#)

Narrative: Log in using your DFUF username and password. Your DFUF login is different from your FURLS/DRLM login.

Step 5

5. If you clicked "New User?" the New User Registration page will open. Select an option and fill in the text box. Then, click **Go**.

Click "I am a new FDA User Fee Organization" if you cannot locate your organization.

New User Registration

The FDA User Fee Website Organization Locator tool allows you to determine whether your organization exists in the FDA User Fee System database. To locate your organization, please provide one of the following options, and click the "Go" button. 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 FDA User Fee System database, please select the "I am a new FDA User Fee Organization" option.

Paid PIN or Cover Sheet Number (e.g., MD6000001-956733, enter 6000001)

Invoice Number

Email Address

Organization Number (unique number assigned by the User Fee System)

Employer ID Number

Dun and Bradstreet Number (DUNS)

I am a new FDA User Fee Organization

Narrative: If you clicked "New User" you will see the FDA User Fee Website Organization Locator Tool. This tool allows you to determine whether your organization exists in the FDA User Fee System database. To locate your organization, check the appropriate option, fill in the corresponding text box, and click "Go." After performing a search, you can select from the Search Results.

If you cannot locate your organization in the FDA User Fee System database, select "I am a new FDA User Fee Organization." For more details, review the FDA User Fee Account Creation User Guide (available under Useful Links).

Step 6

6. Under Annual Establishment Registration, click **Go** on the “MDUFA Establishment Registration User Fee” line to open the Device Facility User Fee page.

User Fee Website
Welcome Steven Nagy

Annual Establishment Registration

User Fee	Description	
MDUFA Establishment Registration User Fee 2014	FURLS Device Facility User Fee	<input type="button" value="Go"/>

Cover Sheets

User Fee	Description	
Animal Drug User Fee 2014*	ADUFA Pre-Market Cover Sheets	<input type="button" value="Go"/>
Animal Generic Drug User Fee 2014*	AGDUFA Cover Sheets	<input type="button" value="Go"/>
Biosimilar User Fee 2014*	BsUFA Cover Sheets	<input type="button" value="Go"/>
Generic Drug Backlog Fee*	GDUFA Backlog Fee Cover Sheets	<input type="button" value="Go"/>
Generic Drug User Fee 2013*	GDUFA Cover Sheets	<input type="button" value="Go"/>
Generic Drug User Fee 2014*	GDUFA Cover Sheets	<input type="button" value="Go"/>

Narrative: When you are logged into the DFUF website, click “Go” next to “MDUFA Establishment User Fee 2014/FURLS Device Facility User Fee” to continue with the payment process.

Step 7

7. On the Device Facility User Fee Page, **enter the number of establishments** and click **Add to Cart**.

The screenshot shows a web page titled "Device Facility User Fee". The page contains the following text:

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. 379i) 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>

You must complete the entire payment and registration process by December 31, 2013. Please provide enough time for payment processing, especially if you are paying by check.

Product	Quantity	Unit Price
Device Facility User Fee	1	\$3,313.00 EACH

Narrative: Enter the number of establishments you are paying for in the Quantity box and click "Add to Cart".

Step 8

8. On the Order page, ensure your quantity is correct. (Click *Recalculate* if you need to change the quantity.) Then, click **Next**.

The screenshot shows an order page with a dark blue header bar containing the text "Device Facility User Fee". Below the header, the word "Order" is displayed. A note with a checkmark icon states: "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." Below this note are two links: "Select All" and "Clear Selections". A table with the following data is shown:

Delete	Product	Quantity	Creation Date	Last Update Date	Total Due
<input type="checkbox"/>	Device Facility User Fee	1	19-NOV-2013 11:31:35	19-NOV-2013 11:31:35	\$3,313.00

Below the table is a "Recalculate" button. At the bottom of the page, a message reads: "This order is in progress. Click the 'Next' button to continue." The "Next" button is highlighted with a red rectangular box.

Narrative: Review for accuracy and click on the "Next" button to continue with the payment process. If you need to change the quantity, click on the "Recalculate" button to update the "Total Due" column and then click "Next".

Step 9

9. Review billing information (**add/edit** address if needed) and click **Next**.

The screenshot shows a web form titled "Device Facility User Fee" with a blue header bar. Below the header, the text "Billing Information" is underlined. The form contains the following text: "Customer: SANCO", "Contact: Steven Nagy", "301-7701234", "steve.nagy@fda.hhs.gov", and "Address: 12345 Rockville Pike", "Rockville,MD 20852", "UNITED STATES". To the right of the address is a button labeled "Add / Edit Address" with a red border. At the bottom right of the form is a button labeled "Next" with a red border.

Narrative: Review the billing information for accuracy. Click Add / Edit to make changes. Then, click "Next" to open the Submit order page.

Step 10

10. Review the order and click **Submit Order** to get your Payment Identification Number (PIN).

The screenshot shows a web form titled "Submit Order" for a "Device Facility User Fee". The form contains a table with one row of order details, a total amount, and sections for customer and billing information. A "Submit Order" button is highlighted with a red box at the bottom right.

Product	Quantity	Creation Date	Last Update Date	Unit Price
FY 2014 Device Facility User Fee	1	19-NOV-2013 11:31:35	19-NOV-2013 11:32:36	\$3,313.00

Total: \$3,313.00

Customer Information
Customer: SANCO
Steven Nagy
301-7701234
steve.nagy@fda.hhs.gov

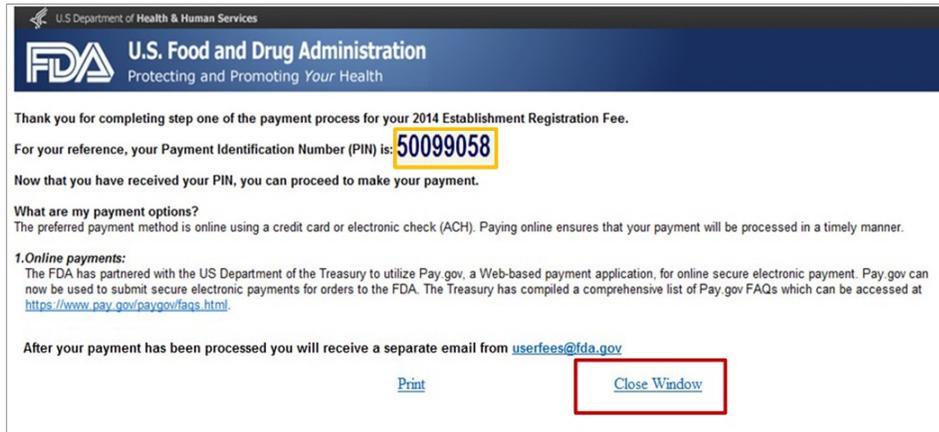
Billing Information
Bill To: Steven Nagy
SANCO
12345 Rockville Pike
Rockville, MD 20852
UNITED STATES

Submit Order

Narrative: Review the order and click on "Submit Order" to get your Payment Identification Number (PIN).

Step 11

11. Your PIN will be displayed in the second sentence. Click Close Window to open Confirmation Page.



The screenshot shows a web page from the U.S. Food and Drug Administration (FDA). The header includes the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". The main content area contains the following text:

Thank you for completing step one of the payment process for your 2014 Establishment Registration Fee.

For your reference, your Payment Identification Number (PIN) is: **50099058**

Now that you have received your PIN, you can proceed to make your payment.

What are my payment options?
The preferred payment method is online using a credit card or electronic check (ACH). Paying online ensures that your payment will be processed in a timely manner.

1. Online payments:
The FDA has partnered with the US Department of the Treasury to utilize Pay.gov, a Web-based payment application, for online secure electronic payment. Pay.gov can now be used to submit secure electronic payments for orders to the FDA. The Treasury has compiled a comprehensive list of Pay.gov FAQs which can be accessed at <https://www.pay.gov/paygov/faqs.html>.

After your payment has been processed you will receive a separate email from userfees@fda.gov

At the bottom of the page, there are two links: "Print" and "Close Window". The "Close Window" link is highlighted with a red rectangular box.

Narrative: Your PIN is shown in the second sentence in this paragraph. You have the option to print the page. Click "Close Window" to open the Confirmation page.

Step 12

12. On the Confirmation page, click **Pay Now**.

Device Facility User Fee

Confirmation

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

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 submit a survey. This will only take about 2 minutes to complete.

Product	Quantity	Creation Date	Last Update Date	Unit Price
FY 2014 Device Facility User Fee Print/View Final Order	1	19-NOV-2013 11:31:35	19-NOV-2013 11:32:36	\$3,313.00

Total: \$3,313.00

YOUR PAYMENT IDENTIFICATION NUMBER (PIN) IS:
50099058

[Pay Now](#) [Create Another Order](#)

Narrative: On the Confirmation page, you can view a copy of your coversheet by clicking on “Print/View Final Order”. Click on “Pay Now” to open the Payment page.

Payment Options

- When payment is processed, you will receive your Payment Confirmation Number (PCN) by email.
- Fastest payment option via credit card, electronic check (ACH), or wire transfer (PIN must be included in wire transfer) takes 2-3 business days after payment date.
- Slowest payment option via mailed check takes 5-7 business days after payment date (PIN must be written on check).

Narrative: You have a number of payment options. The fastest way to pay is credit card, electronic check, or wire transfer. The slower method is by mailed check. You will need to add the PIN number to your mailed checks and wire transfers.

Online Payment

Pay by credit card, wire transfer, or check.

- For electronic check, click “Continue with ACH Payment”.
- For credit card, click “Continue with Plastic Card”.

For more information, click Payment Options.

After your payment is processed, you will receive your Payment Confirmation Number (PCN).

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

Pay Via Bank Account (ACH) [about ACH Debit](#) 1 | 2 | 3

Required fields are indicated with a red asterisk *

Account Holder Name: SANCO *

Payment Amount: \$3,313.00

Account Type: *

Routing Number: *

Account Number: *

Confirm Account Number: *

Check Number:

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

Payment Date: 11/20/2013

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

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

Pay Via Plastic Card (PC) (ex: American Express, Discover, Mastercard, VISA)

Required fields are indicated with a red asterisk *

Account Holder Name: SANCO *

Payment Amount: \$3,313.00

Billing Address: *

Billing Address 2:

City:

State / Province:

Zip / Postal Code:

Country: United States

Card Type:    

Card Number: * (Card number value should not contain spaces or dashes)

Security Code: * [CVV2/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](#)

Narrative: If you pay by electronic check, use the form on the top; for credit card use the form on the bottom. Include the information requested and then click on either "Continue with ACH Payment" for the electronic check or "Continue with Plastic Card" (credit card) to complete the payment process.

Confirmation Email

You will receive an online confirmation and an email confirmation with your Agency Tracking Number.

Note: The Agency Tracking Number is the same as your PIN.

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: FOA USER FEES
Pay.gov Tracking ID: 3FOCDDUO
Agency Tracking ID: 50000146
Transaction Date and Time: 08/08/10:18 EDT

Payment Summary

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

Narrative: After submitting your payment electronically, you will see an online confirmation. You will also be sent a confirmation email. In both the online and email confirmation, you will see the Agency Tracking ID. The Agency Tracking ID is the same as the Payment Identification Number (PIN).

Payment Process/Timeline

- Allow 2-5 business days for electronic payment processing.
- Allow 7-10 business days for check to be processed; PCN will be sent by email.
- Customers that paid the fee will receive an email
- PCN for current fiscal year can only be used to complete registration (Annual, Initial, or Updates) for current fiscal year
- Both the PIN and PCN are required to complete an establishment's registration (annual or initial) or to make changes to your registration.

Narrative: Remember to allow time for your payment to be processed. Once your payment is processed, an email with the Payment Confirmation Number (PCN) will be sent to the email address associated with the account. You will need both your PIN and PCN to register your establishment for the first time (initial), to re-register your establishment (annual) or to make changes to your registration.

Assistance

- Paying annual registration fee: User Fee Helpdesk - 301-796-7200 or userfees@fda.gov
- Completing annual or general registration & listing questions CDRH Registration & Listing Helpdesk - 301-796-7400 (press option 1 to leave a message) or reglist@cdrh.fda.gov
- Import detention issues or registration & listing policy questions CDRH Registration & Listing Policy Helpdesk - 301-796-7400 (press option 2 to leave a message) or device.reg@fda.hhs.gov
- Registering an establishment for the first time (initial registration process): CDRH Registration and Listing Helpdesk -301-796-7400 (option 1) or reglist@cdrh.fda.gov

Narrative: If you need assistance with paying the annual registration user fee, contact the User Fee Helpdesk. If you need assistance with completing the annual registration, contact the CDRH Registration and Listing Helpdesk. If you need assistance with registration and listing policy or detentions, contact the CDRH Registration and Listing Policy Helpdesk.

Helpful Links

Device Registration and Listing <https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing>

Who Must Register, List, and Pay the Fee <https://www.fda.gov/medical-devices/device-registration-and-listing/who-must-register-list-and-pay-fee>

Payment Process <https://www.fda.gov/medical-devices/device-registration-and-listing/payment-process>

Useful Links https://userfees.fda.gov/OA_HTML/furls.jsp?legalsel=2&ref=

Narrative: Please use these helpful links for more information. This concludes the module on paying the annual registration user fee using the DFUF website.