

## Welcome

The screenshot shows the top of a website with a blue header. On the left is the FDA logo with the text "U.S. Food and Drug Administration" and "Protecting and Promoting Public Health". On the right is the URL "www.fda.gov". The main content area has a large, bold title: "Paying the Annual Registration User Fee via the Device Facility User Fee (DFUF) Website". Below the title is the text "U.S. Food and Drug Administration" and "Center for Devices and Radiological Health". On the left side of the page is the CDRH logo, which is circular and contains the text "Center for Devices and Radiological Health" and "CDRH". On the right side, there is a button labeled "Click next" with a hand-drawn arrow pointing to the right.

Narrative: Welcome to Paying the Annual Registration User Fee via the Device Facility User Fee (DFUF) Website tutorial. Click the Next button to begin.

## Agenda

FDA U.S. Food and Drug Administration  
Protecting and Promoting Public Health www.fda.gov

**Resources**

### Agenda

- Introduction
- Device Facility User Fee (DFUF) Website Login Instructions
- Annual Registration User Fee Instructions

### Navigation

As you move through the tutorial, you have the option of viewing the instructions in plain text or with images. For a print copy of the instructions, click the Resources tab on the upper right corner of the player window.

Click Next or Prev to move through the tutorial. You can also use the left menu and click on a specific topic. To adjust or turn off audio, use your computer's volume control. To read the narrative, click on the Notes tab next to the menu.

**Click next for instructions**

Narrative: The 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.

## Introduction



U.S. Food and Drug Administration  
Protecting and Promoting Public Health

www.fda.gov

### Introduction: Annual Registration User Fee

- All medical device establishments are required to register and pay the annual registration user fee.
- The [Medical Device Website](#) posts anticipated fees for current and upcoming Fiscal Years.
- 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.

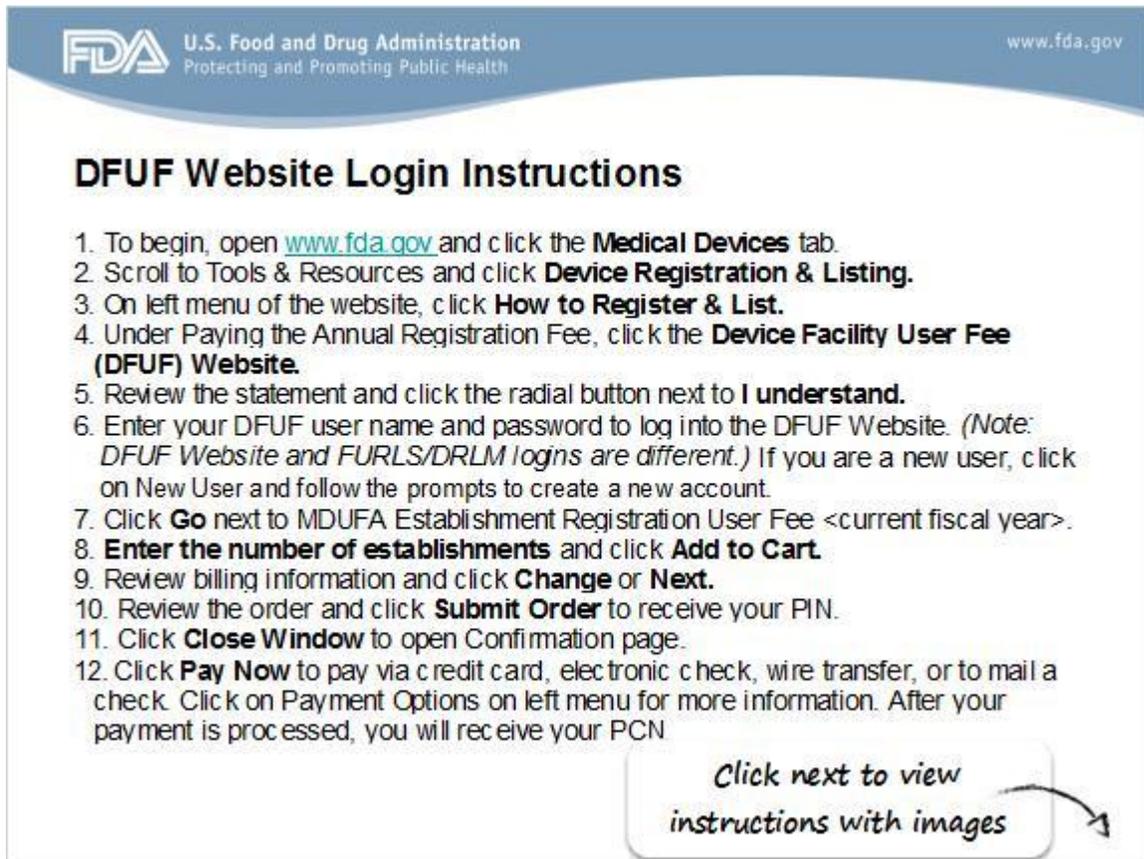


## Annual Registration User Fee

- Payment Identification Number (PIN)
- After payment is processed, an email will be sent with the Payment Confirmation Number (PCN)
- Must have PIN/PCN before accessing FURLS/DRLM

Narrative: During the payment process, you will create an order. Your PIN is provided after you create your order. Your payment confirmation number is emailed to you after you submit your payment. You must have both the PIN and PCN before you can complete the annual registration and/or make changes in the FULRS/DRLM.

## Text instructions



The screenshot shows the FDA website header with the logo and the text "U.S. Food and Drug Administration Protecting and Promoting Public Health" and "www.fda.gov". Below the header is a section titled "DFUF Website Login Instructions" with a list of 12 numbered steps. At the bottom right of the screenshot, there is a callout box with the text "Click next to view instructions with images" and an arrow pointing to the right.

**DFUF Website Login Instructions**

1. To begin, open [www.fda.gov](http://www.fda.gov) and click the **Medical Devices** tab.
2. Scroll to Tools & Resources and click **Device Registration & Listing**.
3. On left menu of the website, click **How to Register & List**.
4. Under Paying the Annual Registration Fee, click the **Device Facility User Fee (DFUF) Website**.
5. Review the statement and click the radial button next to **I understand**.
6. Enter your DFUF user name and password to log into the DFUF Website. (Note: *DFUF Website 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.
7. Click **Go** next to MDUFA Establishment Registration User Fee <current fiscal year>.
8. **Enter the number of establishments** and click **Add to Cart**.
9. Review billing information and click **Change** or **Next**.
10. Review the order and click **Submit Order** to receive your PIN.
11. Click **Close Window** to open Confirmation page.
12. 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.

Click next to view instructions with images

Narrative: To start, click on the fda.gov link to open the website, then follow the instructions. If you would like to view images with the instructions, click Next.

## Instructions with Images



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

1. To start, click on [fda.gov](http://fda.gov) link to open the website, then click on the Medical Devices tab.

2. Scroll down the page to Tools & Resources, and click Registration & Listing to open the Medical Device Registration & Listing homepage.

The screenshot shows the FDA Medical Devices website. The left sidebar contains a navigation menu with the following items: Device Advice: Comprehensive Regulatory Assistance, How to Market Your Device, Medical Device Registration and Listing, Important Reminders about Registration and Listing, Access Electronic Registration and Listing, Who Must Register, List and Pay the Fee, When to Register and List, How to Register and List, Payment Process, U.S. Agents, Frequently Asked Questions about the New Device, and Contact Us. The 'How to Register and List' item is highlighted with a yellow box.

The main content area is titled 'Device Registration and Listing'. It includes a sub-header 'Device Registration and Listing: Get e-mail updates' with a red envelope icon. Below this is a paragraph explaining that owners or operators of medical devices are required to register annually with the FDA. A table shows the schedule of annual registration user fees for fiscal years 2015 through 2017:

|                              | FY 2015 | FY 2016 | FY 2017 |
|------------------------------|---------|---------|---------|
| Annual registration user fee | \$0     | \$3,872 | \$3,872 |

Below the table, there is a section titled 'How to Register and List' with a yellow box around it. Underneath, there is a section titled 'General Information' and 'Paying the Annual Registration Fee'. The 'Paying the Annual Registration Fee' section includes a link to the 'Device Facility User Fee (DFUF) website', which is also highlighted with a yellow box.

Two callout boxes provide instructions: '3. Click How to Register & List' points to the highlighted menu item, and '4. Under Paying the Annual Registration Fee, click Device Facility User Fee (DFUF) Website' points to the highlighted link.

Narrative: 3. On the left menu, click How to Register & List.

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

The screenshot shows the top of the FDA website with the logo and tagline. Below is a legal disclaimer in 18 U.S.C. § 1001. A callout box points to the 'I understand' button, which is highlighted with a yellow border. At the bottom, contact information for the user fee helpdesk is provided.

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 penalties
- (iv) That use of the system indicates consent to monitoring and recording
- (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

**FOR QUESTIONS, PLEASE CONTACT THE USER FEE HELPDESK AT (301) 796-7200 OR USERFEES@FDA.GOV**

Narrative: 5. Review the statement and click "I understand" to open the DFUF Log-in page.

The image shows a screenshot of the FDA User Fee System login page. At the top left is the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". A callout box at the top right states: "FURLS/DRLM & DFUF payment logins are different." Below the header is a "Useful Links" section with a list of links: "User Fee Information", "User Fee Payment Information", "Frequently Asked Questions (FAQs)", "FDA User Fee Account Creation Process User Guide", and "FURLS Cover Sheet Creation Process User Guide". The main content area is titled "Log in to the User Fee System" and contains a login form with "User Name:" and "Password:" labels, two input fields, a "Login" button, and a "Forgot User Name/Password?" link. Below the login form is a link that says "New User? Please create a User Fee account." A callout box at the bottom right of the form area says: "Click New User to create a new account."

Narrative: 6. Log in using your DFUF user name & password.  
Your DFUF login is different from your FURLS / DRLM login.

**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.

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**Paid PIN or Cover Sheet Number**  (e.g., MD5000001-956723, 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**

**Go**

password, please contact the

*Select an option and fill in the corresponding text box...*

*..and click Go.*

*If you cannot locate your organization, 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).*

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).

**User Fee Website**  
Welcome Steven Nagy

**7. Click Go (next to MDUFA Establishment Registration User) to open the Device Facility User Fee page.**

**Annual Establishment Registration**

| User Fee                                       | Description                    |                    |
|--|--------------------------------|--------------------|
| MDUFA Establishment Registration User Fee 2014 | FURLS Device Facility User Fee | <a href="#">Go</a> |

**Cover Sheets**

| User Fee                           | Description                          |                    |
|------------------------------------|--------------------------------------|--------------------|
| Animal Drug User Fee 2014*         | ADUFA Pre-Market Cover Sheets        | <a href="#">Go</a> |
| Animal Generic Drug User Fee 2014* | AGDUFA Cover Sheets                  | <a href="#">Go</a> |
| Biosimilar User Fee 2014*          | BsUFA Cover Sheets                   | <a href="#">Go</a> |
| Generic Drug Backlog Fee*          | GDUFA Backlog Fee Cover Sheets       | <a href="#">Go</a> |
| Generic Drug User Fee 2013*        | GDUFA Cover Sheets                   | <a href="#">Go</a> |
| Generic Drug User Fee 2014*        | GDUFA Cover Sheets                   | <a href="#">Go</a> |
| Medical Device User Fee 2014*      | MDUFA Cover Sheets (PMA, 510k, etc.) | <a href="#">Go</a> |
| Prescription Drug User Fee 2014*   | PDUFA Pre-Market Cover Sheets        | <a href="#">Go</a> |

Narrative: 7. 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.

**Device Facility User Fee**

## Device Facility User Fee

All medical device establishments/facilities that are required to register with the FDA are required to pay the Device Facility User Fee. Section 737 (21 U.S.C. 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/wcm053165.htm>

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

The 2014 registration process includes 3 main steps:

1. Create your order and PIN (payment information)
2. Pay
3. Re-register

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 |

Add to Cart

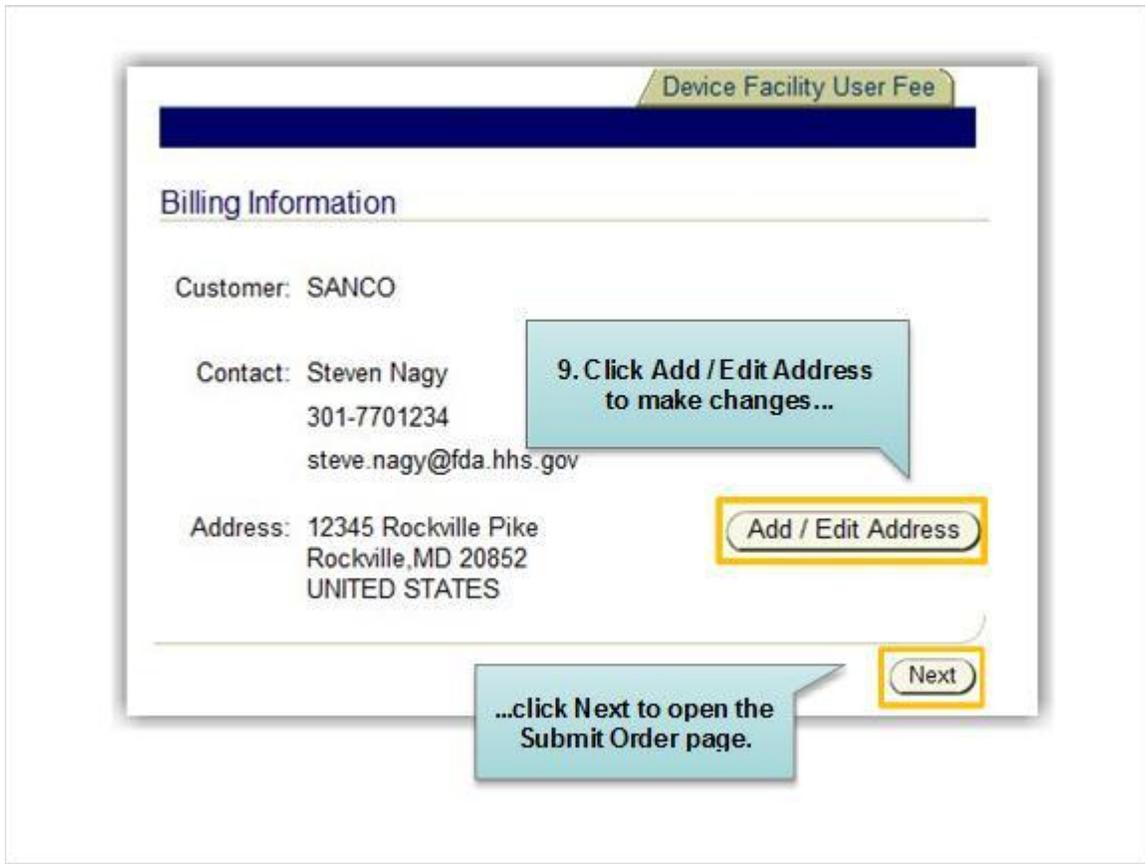
...click Add to Cart to open the Order page.

Narrative: 8. Enter the number of establishments you are paying for in the Quantity box and click "Add to Cart".

The screenshot shows a web application interface for managing an order. At the top right, there is a tab labeled "Device Facility User Fee". Below this, the word "Order" is displayed. A message states: "Do not click the 'Back' button in your browser to adjust your quantity. Instead, then click the 'Recalculate' button." Below this message are two links: "Select All" and "Clear Selections". A table with the following columns is visible: "Delete", "Product", "Quantity", "Creation Date", and "Total Due". The table contains one row with the following data: a checkbox, "Device Facility User Fee", "1", "19-NOV-2013 11:31:35", and "63,313.00". A "Recalculate" button is located to the right of the table. Below the table, a message says: "This order is in progress. Click the 'Next' button to continue." A "Next" button is located to the right of this message. Two callout boxes provide instructions: one points to the "Recalculate" button with the text "If you change your quantity on the Order, click Recalculate to update Total Due." and another points to the "Next" button with the text "Click Next to open the Checkout page."

| Delete                   | Product                  | Quantity | Creation Date        | Total Due |
|--------------------------|--------------------------|----------|----------------------|-----------|
| <input type="checkbox"/> | Device Facility User Fee | 1        | 19-NOV-2013 11:31:35 | 63,313.00 |

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".



Narrative: 9. Review the billing information for accuracy. Click Add / Edit to make changes. Then, click "Next" to open the Submit order page.

Device Facility User Fee

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Submit Order

| 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               |
|                                  |          |                      |                      | <b>Total: \$3,313.00</b> |

**Customer Information**

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

**Billing Information**

Bill To: Steven Nagy  
 SANCO  
 12345 Rockville  
 Rockville, MD 20  
 UNITED STATES

**10. Review the order and click Submit Order to get your PIN.**

Narrative: 10. Review the order and click on "Submit Order" to get your Payment Identification Number (PIN).

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

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

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.

**f. 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>

Pay.gov provides customers the option to submit online payment via credit card (VISA, MasterCard, AMEX or Discover) or Automated Clearing House (ACH) electronic check (eCheck). After submitting your order, click the **'Pay Now'** button and follow the on-screen instructions to make payment. You can close this window to return to the User Fee Website to continue with your online payment. To pay later, log into your DFUP User Fee account and access your order history page by clicking on the **'Previous Orders/PCN'** icon at the top of the page. Click the **'Pay Now'** link next to the PIN you need to pay for. Confirmation of payment made by credit card/electronic check can be received in as little as 48 hours.

**Note:** If you submit your payment online, you will receive a Pay.gov Tracking ID from Pay.gov indicating that your payment has been received. If you do not receive a payment confirmation, please allow 2-3 business days for the FDA to process your online payment. You will receive a confirmation once your PCN is available.

Once you make your payment, allow at least 2-3 business days for FDA to process online payments and 5-7 business days for FDA to process paper checks.

After your payment has been processed you will receive a separate email from [userfee@fda.gov](mailto:userfee@fda.gov)

[Print](#) [Close Window](#)

**11. Click Close Window to open Confirmation page.**

**Your PIN is displayed in the second paragraph.**

Narrative: 11. 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.

Device Facility User Fee

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**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<br><a href="#">Print/View Final Order</a> | 1        | 19-NOV-2013 11:31:35 | 19-NOV-2013 11:32:36 | \$3,313.00               |
|  |          |                      |                      | <b>Total: \$3,313.00</b> |

**Payment IDENTIFICATION NUMBER (PIN) IS:**  
**50099058**

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

[What are my payment options?](#)

Narrative: 12. 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***



The header of the slide features the FDA logo on the left, the text "U.S. Food and Drug Administration" and "Protecting and Promoting Public Health" in the center, and the website "www.fda.gov" on the right. The background is a light blue gradient with a white wavy border at the bottom.

### **Payment Options**

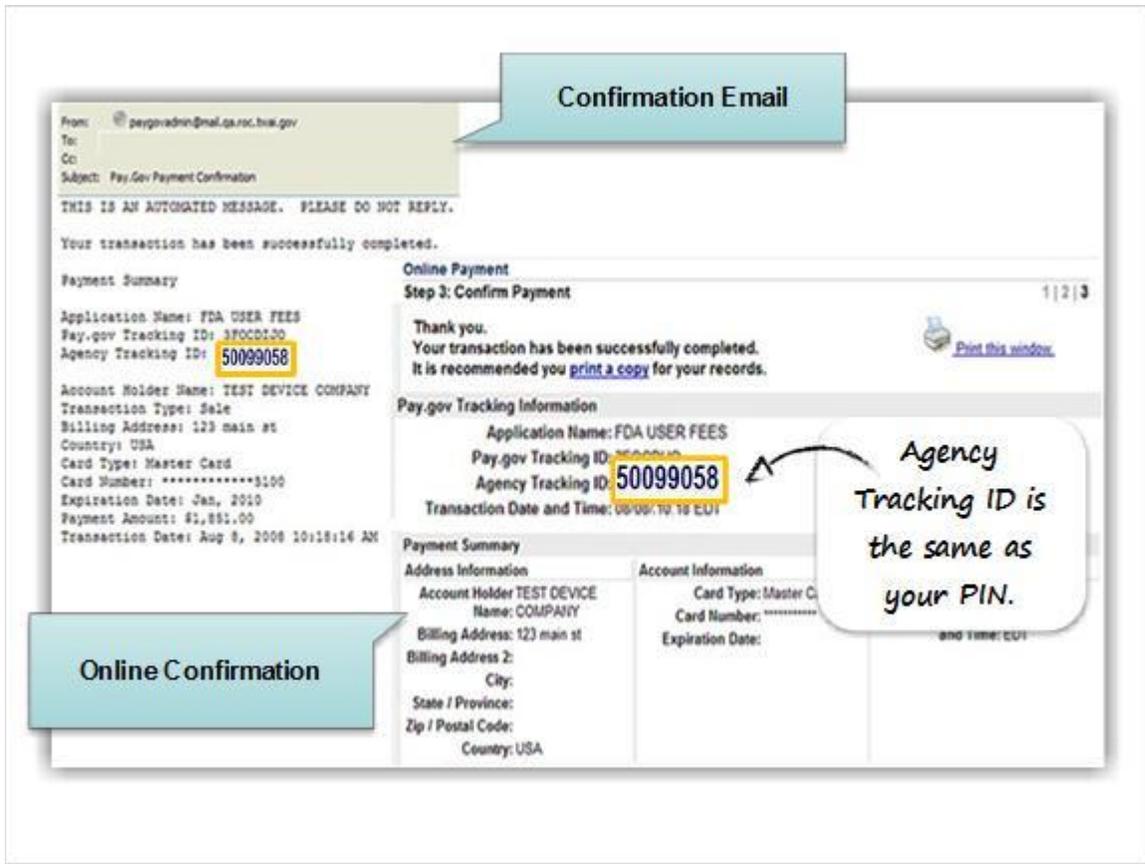
- When payment is processed, you will receive your Payment Confirmation Number (PCN) by email.
- Fastest payment option via credit card, electronic check (ACH), or wire transfer (PIN must be included in wire transfer) takes 2-3 business days after payment date.
- Slowest payment option via mailed check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

The image shows a screenshot of a payment system interface with two main sections. The top section is titled 'Electronic Check Form' and contains a 'System Message' at the top, followed by a 'Payment Information' section. This section includes fields for 'Account Holder Name' (SANCO), 'Payment Amount' (\$3,313.00), 'Account Type', 'Routing Number', 'Account Number', 'Confirm Account Number', and 'Check Number'. Below these fields are two boxes for 'Routing Number' (026946763) and 'Account Number' (9243767390). A 'Continue with ACH Payment' button is highlighted in yellow. A callout box on the right says: 'For electronic check, add requested information, then click Continue with ACH (electronic check) Payment to complete payment.'

The bottom section is titled 'Credit Card Form' and contains a 'Payment Information' section. It includes fields for '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' (with VISA, MasterCard, and American Express logos), 'Card Number', 'Security Code', and 'Expiration Date'. A 'Continue with Plastic Card Payment' button is highlighted in yellow. A callout box on the right says: 'For credit card, add requested information, then, click Continue with Plastic Card (credit card) Payment to complete payment.'

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.



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



U.S. Food and Drug Administration  
Protecting and Promoting Public Health

www.fda.gov

### 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 email
- 2014 PCNs will start with 14
- 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



U.S. Food and Drug Administration  
Protecting and Promoting Public Health

www.fda.gov

### Assistance

If you need assistance, contact the following resources:

**Paying annual registration fee**  
User Fee Helpdesk  
Phone: 301-796-7200  
Email: [userfees@fda.gov](mailto:userfees@fda.gov)

**Completing annual or general registration & listing questions**  
CDRH Registration & Listing Helpdesk  
Phone: 301-796-7400 (press option 1 to leave a message)  
Email: [reglist@cdrh.fda.gov](mailto:reglist@cdrh.fda.gov)

**Import detention issues or registration & listing policy questions**  
CDRH Registration & Listing Policy Helpdesk  
Phone: 301-796-7400 (press option 2 to leave a message)  
Email: [device.reg@fda.hhs.gov](mailto:device.reg@fda.hhs.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



The screenshot shows the top of the FDA website with the logo and tagline 'U.S. Food and Drug Administration Protecting and Promoting Public Health' and the URL 'www.fda.gov'. Below this is a section titled 'Helpful Links' containing three entries, each with a title and a URL:

- Device Registration and Listing**  
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm>
- Who Must Register, List, and Pay the Fee**  
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm>
- Payment Process**  
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053186.htm>

Below these is a section titled 'Useful Links' with the URL:

[https://userfees.fda.gov/OA\\_HTML/furls.jsp?legalse1=2&ref=](https://userfees.fda.gov/OA_HTML/furls.jsp?legalse1=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.