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 page and click Paying the Annual Registration Fee.

How to 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.

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.

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.*
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.

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

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**.

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**.

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**.

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).

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.

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**.

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).

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.*

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**


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