Welcome

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

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

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

- 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.

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

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

Government website login instructions:
1. To begin, open 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 your 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.

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 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.
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.
Narrative: 5. Review the statement and click "I understand" to open the DFUF Log-in page.
Narrative: 6. Log in using your DFUF user name & password. Your DFUF login is different from your FURLS / DRLM login.
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).
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.
Narrative: 8. Enter the number of establishments you are paying for in the Quantity box and click “Add to Cart”.
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.
Narrative: 10. Review the order and click on “Submit Order” to get your Payment Identification Number (PIN).
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.
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

- 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.
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) Payment" 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

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

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.

Paying annual registration fee
User Fee Helpdesk
Phone: 301-796-7200
Email: 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: regist@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

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
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/ucm053185.htm

Payment Process
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053186.htm

Useful Links
https://userfees.fda.gov/OA_HTML/furls.jsp?legalsection=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.