



User Fee System (UFS)

User Fee iStore Account Creation

Desk Guide

Overview

This desk guide provides step-by-step instructions for creating an iStore account. The process includes steps that assist the user in determining if their organization already exists in UFS, prior to creating a new iStore account.

To create a new iStore account, follow these steps:

1. Access the appropriate User Fee website.
2. Review the statement and click the “**I understand**” radio button (Figure 1).

Figure 1: FDA Access Conditions Page



- You are navigated to the User Fee login page. If you do not have an existing user fee account, click the **New User? Please register...** link (Figure 2).

At the end of fiscal year (FY) 2020, FDA will change its policies regarding the transfer of payments across fiscal years to align with the Treasury Accounting Treatment Manual. The Agency will refund payments made to user fee cover sheet ID that are not linked to a submitted application in the previous FY. Applicants with any payment from a prior year without a corresponding application submission should submit a refund request. To request a refund, complete [Form FDA 3913](#) and email the form to OPENCollections@fda.hhs.gov and userfees@fda.gov. Form FDA 3913 is available at <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM492189.pdf>.

Starting in FY 2021, a payment made to a user fee cover sheet within the FY that is not linked to an application submitted in that FY will not be transferred to the new FY. Previous FY payment without an application submission will be refunded and the applicant will have to submit a new user fee cover sheet with a new payment for the new FY.

Payment transfers occurring within the same FY will not be affected by this change in policy. If you have any questions regarding this change, please contact the User Fee Staff at userfees@fda.gov.

Useful Links

- [User Fee Information](#)
- [User Fee Payment Information](#)
- [Frequently Asked Questions \(FAQs\)](#)
- [FDA User Fee Account Creation: Step-by-Step Instructions](#)
- [MDUFA 510\(k\) Cover Sheet Creation: Step-by-Step Instructions](#)
- [MDUFA 513g Cover Sheet Creation: Step-by-Step Instructions](#)
- [MDUFA PMA Cover Sheet Creation: Step-by-Step Instructions](#)
- [MDUFA De Novo Request Cover Sheet Creation: Step-by-Step Instructions](#)

Note: The step-by-step instructions for cover sheet creation is specific to each user fee program

Log in to the User Fee System

[Login to Enterprise ICAM](#)

[Forgot User Name/Password?](#)

[New User? Please register...](#)

User Fee System Alerts

Effective October 1, 2010, FDA implemented new procedures for payment of the MDUFA Annual Fee for Periodic Reporting. As a result, customers are no longer able to create a User Fee Cover Sheet to pay their Annual Fee for Periodic Reporting.

Instead, customers will be sent an invoice at the end of the quarter in which their PMA periodic report is due. Your invoice will include all the payment submission details required to make your payment.

Further details are provided in the [FAQs](#).

Please note the FDA's user fee credit card limit is \$24,999.99. You will not be able to make an online payment with a credit card for payments over this limit. The ACH online payment option is still available for amounts exceeding the credit card limit.

For customers who need to register their Medical Device Facility, please access the [Electronic Registration & Listing System \(EURLS\)](#).

Need Help? Click Here For Assistance.

Figure 2: User Fee Login Page

- You will be taken to the *New User Registration* page (Figure 3), where you can search for your organization. There are six search options to select from in order to determine if your organization exists in UFS. Conduct a search for your organization **before** clicking the “I am a new FDA User Fee Organization” radio button. The six search options are:
 - Paid PIN or Cover Sheet Number:** If you have a previous year’s Payment Identification Number (PIN) or Cover Sheet Number, please select this radio button and enter the PIN or cover sheet number in the **Paid PIN or Cover Sheet Number** field, and then click the **Go** button .
 - Invoice Number:** If you have a previous year’s Invoice Number, please select this radio button and enter the invoice number in the **Invoice Number** field, and then click the **Go** button .
 - E-mail Address:** If an e-mail address was used to pay for FDA user fees in the past, select this radio button and enter the e-mail address in the **Email Address** field, and then click the **Go** button .
 - Organization Number:** The organization number is a unique number assigned to your organization by the UFS.
 - If you don’t know your organization number, contact the [User Fee](#)



[Helpdesk](#) for assistance. Also, if you have received a Small Business Decision (SBD) letter from the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), the organization number can be found in the letter.

- b. If you know your organization number, please select this radio button and enter the number in the **Organization Number** field, and then click the **Go** button .
- **Employer ID Number:** If you are a domestic (U.S.-based) entity, select this radio button and enter your entity's Tax Identification Number (TIN) or Employer Identification Number (EIN) in the **Employee ID Number** field, and then click the **Go** button .
 - **Data Universal Numbering System (DUNS):** The DUNS number is nine-digit unique identifier used by the Federal government to identify business entities. If you are a foreign/international (non-U.S.-based) entity, select the **Dun and Bradstreet Number (DUNS)** radio button and enter your entity's DUNS number in the **Dun and Bradstreet Number (DUNS)** field, and then click the **Go** button .

New User Registration

The FDA Division of User Fees has partnered with Dun & Bradstreet (D&B) to allow new FDA User Fee customers to locate their organization in the D&B database. If your organization's information is found in the D&B database, it will be pre-populated as you complete the User Fee Website registration process.

To locate your organization, please provide the information requested below, and click the "Go" button. Fields marked with an asterisk are required. **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 D&B database, please select the "I am a new Organization" option to manually input your organization's information.

Business Name *	<input type="text"/>
DUNS Number	<input type="text"/>
Country *	United States <input type="button" value="v"/>
City *	<input type="text"/>
State *	Select a State <input type="button" value="v"/>

Figure 3: New User Registration Page



5. After performing a search for your organization using one of the six search options, the search results will display directly below the **Go** button . See examples shown in Figure 4 and Figure 5:

Search Results				
If you can locate your organization from the results below, please click the corresponding "Select" button.				
If the results are not applicable, please perform a new search.				
Organization Name	Address	EIN	DUNS	Action
ABC TEST COMPANY	8455 Colesville Lane Silver Spring MD US	*****6789	987654321	<input type="button" value="Select"/>
CDER OM	12001 New Hampshire Silver Spring MD US	*****7878	987654321	<input type="button" value="Select"/>
ORTHOLUTION CO LTD	#104 Suntechcity B/D, 513-15 Joongwen-Gu Seongnam-Si KR		987654321	<input type="button" value="Select"/>
TEST CO	123 test burke va US	*****9090	987654321	<input type="button" value="Select"/>

Figure 4: Positive Organization Search Results

Search Results
Your search did not produce any results. Please select another option and perform a new search.
For additional assistance with finding your organization, creating an account, or retrieving your existing user name and password, please contact the User Fee Helpdesk at 301-796-7200 or email userfees@fda.gov

Figure 5: Negative Organization Search Results

- a. If multiple search results display, select the appropriate result for your organization and click the **Select** button . Proceed to Step 6 to register as a new user for your organization.
 - b. If no search results display (Figure 5), click the **“I am a new FDA User Fee Organization”** radio button and click the **Go** button to initiate registering your organization into UFS. Proceed to Step 7 to continue with the registration process.
6. If your organization displayed in the initial search results and you clicked the **Select** button , you are navigated to the *Business User Registration* page (Figure 6). Your organization’s business information is displayed within the “Business Information” section. In the “User Information” section, enter your user information, then click the **Submit** button . Note the following:
- Fields marked with an asterisk (“*”) are required
 - The first field for the telephone and fax numbers are for the country code
 - Your UFS username may only contain letters and numbers



If you successfully registered as a new user, you are navigated to the UFS website (Figure 11), where your user name and available cover sheets are displayed.

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration
Protecting and Promoting *Your Health*

Business User Registration

* Indicates required field Submit

Business Information

Organization Name: ABC TEST COMPANY
 Organization Number: 412221
 Organization Federal Employer Identification Number: ****6789
 Organization DUNS: 987654321

User Information

* First Name:
 Middle Name:
 * Last Name:
 * Email Address:
 * Confirm Email Address:
 * Day Phone Number: Country Area Code Phone Number Ext.
 Evening Phone Number: Country Area Code Phone Number Ext.
 Fax Number: Country Area Code Phone Number Ext.
 * User Name:
 * Password:
 * Confirm Password:

Important Notice: You must provide a valid email address for FDA to reach you regarding any payment issues, refunds, or other notices.
 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: @, #, \$, %, ^, &, *; !

Submit

Figure 6: Business User Registration Page

7. If you clicked the “**I am a new FDA User Fee Organization**” radio button in Step 5, you are navigated to the *New User Registration* page (Figure 7). Perform a second search of your organization through the Dun and Bradstreet (D&B) System via the User Fee website by entering the following:


- **Organization name:** This is a required field. Enter your organization name in the **Business Name** field. Do not to use any special characters e.g., asterisks, ampersands, periods, commas, etc.) when entering the company name.
- **DUNS Number** field: This is not a required field. Enter your organization’s Data Universal Numbering System (DUNS) number.
- **Country** field: This is a required field. Select the country in which your organization is located from the dropdown list.
- **City** field: This is a required field. Enter the name of the city in which your organization is located.




- **State field:** This is a required field. Select the U.S. state in which your organization is located from the dropdown list.

The screenshot shows the 'New User Registration' page. At the top, there is a header with the FDA logo and the text 'U.S. Food and Drug Administration Protecting and Promoting Your Health'. Below the header are three icons: a question mark for 'FAQ', a person for 'User Fees', and a person with a checkmark for 'Sign In'. The main heading is 'New User Registration'. Below this, there is a paragraph explaining the partnership with Dun & Bradstreet (D&B) and a note that fields marked with an asterisk are required. A 'Go' button is located at the bottom right of the form area. A red box highlights the 'Business Name *', 'DUNS Number', and 'State *' fields.

Figure 7: New User Registration Organization Search

After entering the above information, click the **Go** button .

- If UFS is unable to locate your organization, the “Search Results” section will state that UFS was unable to produce any results (Figure 8). Perform one of the following steps:
 - Perform a new search following the aforementioned steps
 - Navigate to the D&B website to register your organization and obtain a DUNS number
 - Click the **Select** button  to navigate to the *Business User Registration* page.

New User Registration

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To locate your organization, please provide the information requested below, and click the "Go" button. Fields marked with an asterisk are required. 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 D&B database, please select the "I am a new Organization" option to manually input your organization's information.

Business Name *
 DUNS Number
 Country *
 City *
 State *

Search Results

Your search did not produce any results. Please perform a new search or go to www.dnb.com to register your business and get a D&B D-U-N-S Number.
 Otherwise, please select the "I am a new Organization" option to manually input your organization's information.

Organization Name	Address	DUNS	Action
I am a new Organization			<input type="button" value="Select"/>

For additional assistance with finding your organization, creating an account, or retrieving your existing user name and password, please contact the User Fee Helpline at 301-796-7200 or email userfees@fda.gov

Figure 8: Negative Organization Search Results

- b. If UFS is able to locate your organization, proceed to creating a new customer account following Step 7.
8. One you click the **Select** button for "I am a new Organization," you are navigated to the *Business User Registration* page. Enter the required following these steps:
- a. Within the "Business Information" section (Figure 9), enter the **required** information in the following fields:
 - Organization Name
 - Organization Federal Employer Identification Number
 - Country
 - Address (line 1)
 - City
 - State
 - Zip



Business User Registration

* Indicates required field

Business Information

* Organization Name:

* Organization Federal Employer Identification Number:

Organization DUNS:

* Country:

* Address Line 1:

Address Line 2:

Address Line 3:

Address Line 4:

* City:

County:

* State:

* Zip:

User Information

* First Name:

Middle Name:

* Last Name:

Figure 9: Business Information section

- b. Within the “User Information” section, enter the required information following Step 6.
- c. After completing your entry, verify the information, and then click the **Submit** button . You are then navigated to the User Registration Confirmation Page ([Figure 10](#)) displays.

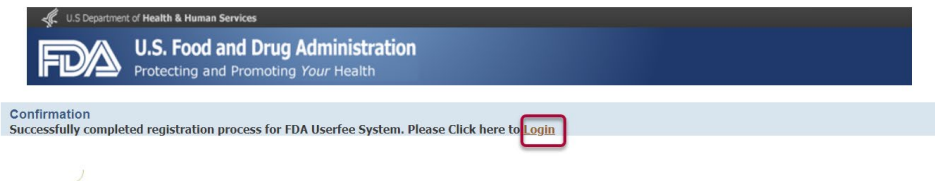


Figure 10: User Registration Confirmation for New UFS User

9. Click the Login hyperlink [Login](#) to Login to your UFS account, you are navigated to the “system use message” page. Select the radio button next to "I understand" to continue.

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.

Figure 11: System Use Message for UFS User

10. Click the [Login to Enterprise ICAM](#) hyperlink to Login to your UFS account, you are navigated to the “Enterprise ICAM Login Page” page.

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

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Useful Links

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- [User Fee Payment Information](#)
- [Frequently Asked Questions \(FAQs\)](#)
- [FDA User Fee Account Creation: Step-by-Step Instructions](#)
- [ADUFA Cover Sheet Creation: Step-by-Step Instructions](#)

[System for Award Management](#)

If you are a domestic entity and are requesting a refund, we recommend that you create an account with the System for Award Management (SAM). SAM validates the registrant information and electronically shares the encrypted data securely with the FDA to facilitate your refund. Click [here](#) to access SAM.

[Privacy Act Notice](#)

[Vulnerability Disclosure Policy](#)

Log in to the User Fee System

[Login to Enterprise ICAM](#)

[Forgot User Name/Password?](#)

[New User? Please register...](#)

User Fee System Alerts

Please note the FDA's user fee credit card limit is \$24,999.99. You will not be able to make an online payment with a credit card for payments over this limit. The ACH online payment option is still available for amounts exceeding the credit card limit.

Figure 12: Login to User Fee System

11. Enter the “Username “to login to your UFS account, click on “Next” button you are navigated to the “Password” entry page.



Sign In to FDA system

 →
[Reset Password](#)

Figure 13: Enterprise ICAM Login Page to enter Username.

12. Enter the “Password” to login to your UFS account, click on “Next” button you are navigated to the “Send Verification Code” screen.

Sign In to FDA system

 ← →
[Reset Password](#)

Figure 14: Enterprise ICAM Login Page to enter Password.

13. Click “Send Code” button to receive OTP to your Registered email address. After clicking on “Send Code” button you will be navigated to Verification Code Sent Screen.


Send Verification Code

Your verification code will be sent to [redacted email address]
Please check your email for the code.

Figure 15: Enterprise ICAM Login Send OTP.

14. You will receive an email with “OTP” code to your registered email address.

Your One Time Passcode (OTP)

 To: [redacted]@fda.hhs.gov

Reply Reply All Forward Wed 3/20/2024 1:49 PM

To authenticate, please use the following One Time Password (OTP):

123456

It expires in 15 minutes.

Don't share this OTP with anyone. Contact User Fee Helpdesk USERFEES@FDA.GOV if you haven't requested it.

Figure 16: Enterprise ICAM Login - OTP email.

15. Return to “Verification Code Sent” screen and enter the “OTP” code received into your registered email address. Click on “Submit Code” button.

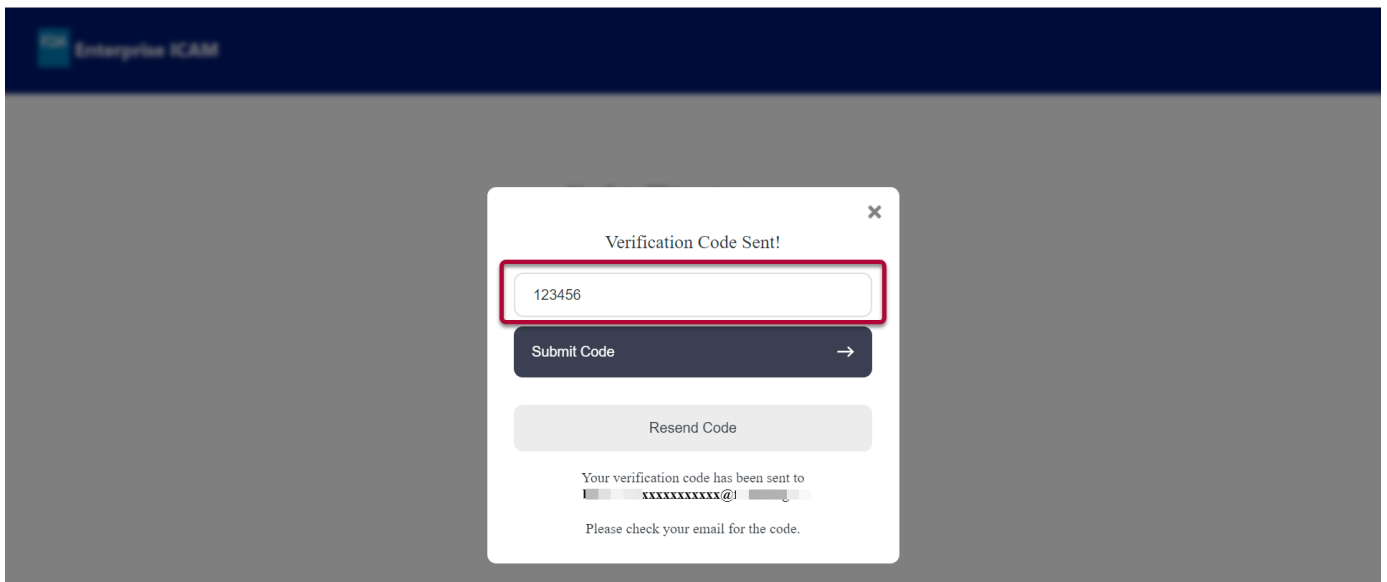


Figure 17: Enterprise ICAM Login - Submit OTP.

16. You are then logged into the User Fee Website and the FDA User Fees main page (**Figure 18**) displays.

User Fee Website
 Welcome FDA Test User

Annual Establishment Registration
 FY 2024 MDUFA Establishment Registration User Fee cover sheets should be created for payments associated with registrations for the period October 1st, 2023 through September 30th, 2024.

User Fee	Description	
MDUFA Establishment Registration User Fee 2024	FURLS Device Facility User Fee	Go

2024 Cover Sheets
 FY 2024 cover sheets should be created for payments associated with submissions to the FDA for the period October 1st, 2023 through September 30th, 2024.

User Fee	Description	
ANIMAL DRUG USER FEE 2024	ADUFA Pre-Market Cover Sheets	Go
ANIMAL GENERIC DRUG USER FEE 2024	AGDUFA Cover Sheets	Go
Biosimilar User Fee 2024	BsUFA Cover Sheets	Go
Generic Drug User Fee 2024	GDUFA Cover Sheets	Go
Medical Device User Fee 2024	MDUFA Cover Sheets (PMA, 510k, etc.)	Go
OTC Monograph User Fee 2024	OMUFA Cover Sheets (OMOR Only)	Go
Prescription Drug User Fee 2024	PDUFA Pre-Market Cover Sheets	Go

2023 Cover Sheets
 FY 2023 cover sheets should be created for payments associated with submissions to the FDA for the period October 1st, 2022 through September 30th, 2023.

User Fee	Description	
OTC Monograph User Fee 2023	OMUFA Cover Sheets (Facility Only)	Go

Figure 18: Welcome Page for New UFS User

If you have any questions regarding the UFS Customer Account process, please contact the User Fees Helpdesk at userfees@fda.gov or (301) 796-7200.