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

3. 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).

Figure 2: User Fee Login Page

4. 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.
  a. If you don't know your organization number, contact the User Fee

Helpdesk for assistance. Also, <u>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</u>.

    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 *	
DUNS Number	
Country *	United States
City *	
State *	Select a State

Go

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 [Go]. 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	Select
CDER OM	12001 New Hampshire Silver Spring MD US	*****-7878	987654321	Select
ORTHOLUTION CO LTD	#104 Suntechcity B/D, 513-15 Joongwen-Gu Seongnam-Si KR		987654321	Select
TEST CO	123 test burke va US	*****-9090	987654321	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 [Select]. 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 [Go] 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 [Select], 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 [Submit]. 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.

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.

Figure 7: New User Registration Organization Search

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

a. 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 [Select] to navigate to the *Business User Registration* page.

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 [Select] 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

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 ▭Submit▭ . You are then navigated to the User Registration Confirmation Page ([Figure 10](#)) displays.
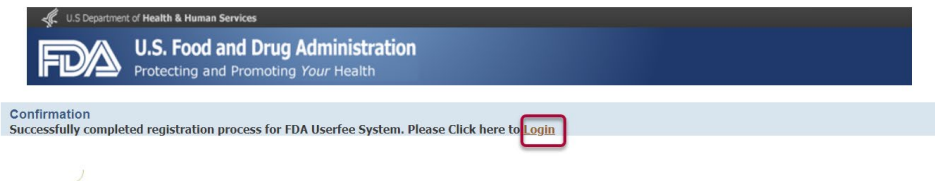

Figure 10: User Registration Confirmation for New UFS User

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.

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.

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

FDAMFATEST

Next →

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

....

< Next →

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

Send Code

Your verification code will be sent to
xxxxxxxxxxxxxxxx@xxxx.xxx.xx
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.

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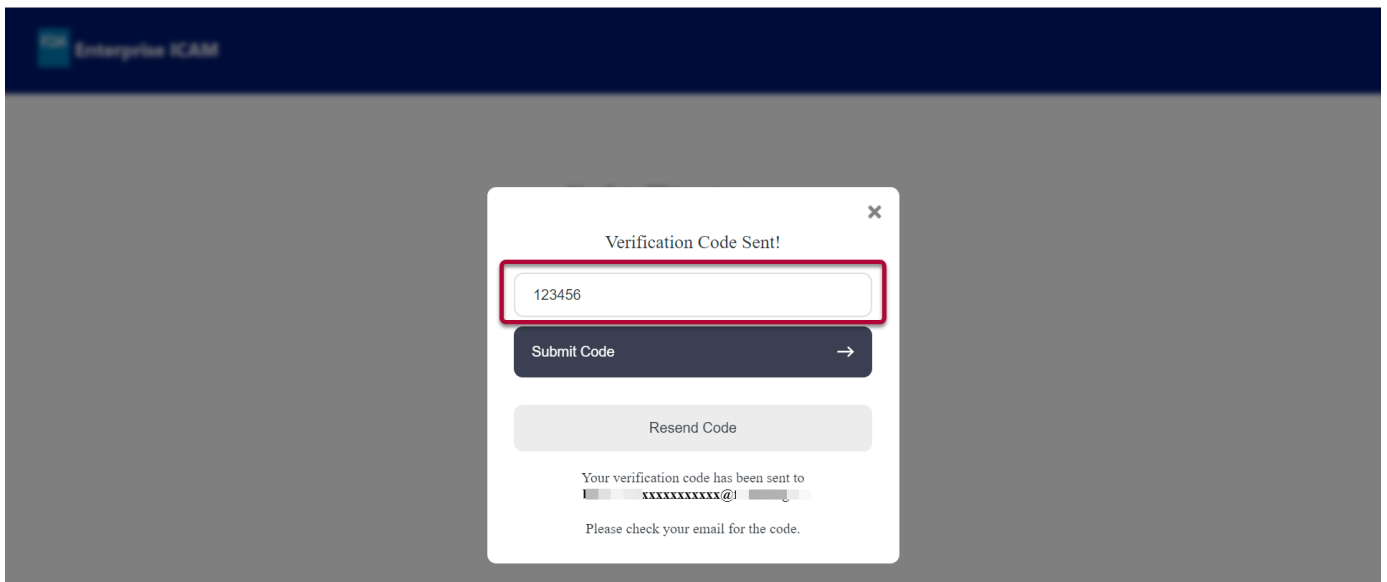FY 2024 MDUFA Establishment Registration User Fee cover sheets should be created for payments associated with registrations for the period October 1st, 2023 through September 30th, 2024.

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.