



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, 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 *

DUNS Number

Country *

City *

State *

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 user name 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.

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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.

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[FAQ](#) [User Fees](#) [Sign In](#)

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 * United States

City *

State * Select a State

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 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 logged into the User Fee Website and the FDA User Fees main page (Figure 10) displays.



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User Fee Website

Welcome Fee User

Annual Establishment Registration

User Fee	Description	
MDUFA Establishment Registration User Fee 2016	FURLS Device Facility User Fee	<input type="button" value="Go"/>

2015 Cover Sheets

FY 2015 cover sheets should be created for payments associated with submissions to the FDA for the period October 1st, 2014 through September 30th, 2015.

User Fee	Description	
Generic Drug User Fee 2015	GDUFA Cover Sheets	<input type="button" value="Go"/>

2016 Cover Sheets

FY 2016 cover sheets should be created for payments associated with submissions to the FDA for the period October 1st, 2015 through September 30th, 2016.

User Fee	Description	
Animal Drug User Fee 2016	ADUFA Pre-Market Cover Sheets	<input type="button" value="Go"/>
Animal Generic Drug User Fee 2016	AGDUFA Cover Sheets	<input type="button" value="Go"/>
Biosimilar User Fee 2016	BsUFA Cover Sheets	<input type="button" value="Go"/>
Generic Drug User Fee 2016	GDUFA Cover Sheets	<input type="button" value="Go"/>
Medical Device User Fee 2016	MDUFA Cover Sheets (PMA, 510k, etc.)	<input type="button" value="Go"/>
Prescription Drug User Fee 2016	PDUFA Pre-Market Cover Sheets	<input type="button" value="Go"/>

Figure 10: 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.

Last updated on 23 November 2015

