Food and Drug Administration



FDA Electronic Submissions Gateway Account Management Portal User Guide

Document Version Date: 08/12/2022

Table of Contents

Contents

Table of Contents	ii
1. Introduction	
1.1. Background	
1.2. Purpose and Audience	1
1.3. General Information on how to use the Accounts Management Portal	
2. Portal Features	2
2.1. Registration	2
2.1.1. WebTrader User Account Registration	2
2.1.1.1. Contact Information	3
2.1.1.2. Company Information	3
2.1.1.3. Documents/Certificate Information	4
2.1.2. Power User Account Registration	5
2.1.2.1. Contact Information	5
2.1.2.2. Company Information	6
2.2. Forgot User ID or Password	6
2.2.1. Forgot Password	6
2.2.2. Forgot User ID	7
2.3. Features for WebTrader Users	9
2.3.1. Search Status of Submissions	9
2.3.2. Send a Submission in ESG Test	10
2.3.3. Send a Submission in ESG Production	11
2.3.4. Update Profile	12
2.3.5. Update Password	14
2.3.6. Upload New Non-Repudiation Letter	15
2.3.7. Upload New Authorization Letter	16
2.3.8. Upload New Certificate	18
2.3.9. Request a Power User Account	20
2.3.10. View Account Status	21
2.4. Features for Power Users	22
2.4.1. Search Status of Submissions	22
2.4.2. Update Profile	24
2.4.3. Update Password	25
2.4.4. Update Company Profile	26

2.4.5.	Upload New Non-Repudiation Letter for Company	28
2.4.6.	Upload New Authorization Letter for Company	29
2.4.7.	Search and Update Company Accounts	31
2.4.7.	1. Update Profile of a Company Account	32
2.4.7.	2. Upload Non-Repudiation Letter for a Company Account	34
2.4.7.	3. Upload Authorization Letter for a Company Account	34
2.4.7.	4. Upload Certificate for a Company Account	35
2.4.7.	5. Update Status of a Company Account	35
2.4.8.	Request a WebTrader Account	36
2.5. Fea	tures for a Power User+ (PU+)	39
2.5.1.	Search Status of Submissions	39
2.5.2.	Send a Submission in ESG Test	40
2.5.3.	Send a Submission in ESG Production	41
2.5.4.	Update Profile	42
2.5.5.	Update Password	44
2.5.6.	Upload New Non-Repudiation Letter (for own Account)	45
2.5.7.	Upload New Authorization Letter (for own Account)	46
2.5.8.	Upload New Certificate (for own Account)	47
2.5.9.	Update Company Profile	49
2.5.10.	Upload New Non-Repudiation Letter for Company	50
2.5.11.	Upload New Authorization Letter for Company	51
2.5.12.	Search and Update Company Accounts	53
2.5.12	2.1. Update Profile of a Company Account	54
2.5.12	2.2. Upload Non-Repudiation Letter for a Company Account	55
2.5.12	2.3. Upload Authorization Letter for a Company Account	56
2.5.12	2.4. Upload Certificate for a Company Account	57
2.5.12	2.5. Update Status of a Company Account	57
2 5 13	View own Account Status	5.8

1. Introduction

1.1. Background

The Accounts Management Portal application has been developed to enhance Industry's user experience with onboarding external Electronic Submissions Gateway (ESG) accounts. It automates Industry account registration and approval process to streamline account onboarding and reduce onboarding time. It allows single access to multiple ESG environments and provides Account Management self-service functionality such as password resets, certificate updates or uploads. It also allows Industry power users to manage user accounts and track submission status.

1.2. Purpose and Audience

The Accounts Management Portal User Guide is a reference document for the Account Management Portal project. The intended audience is the WebTrader (WT) and the Power User (PU). This user guide describes and illustrates the different features of the Portal, based on the user role. A user may utilize this guide by reading the section corresponding to the user role and feature being considered or worked on.

1.3. General Information on how to use the Accounts Management Portal

The Accounts Management Portal has intuitive, easy user interfaces. An initial screen allows the user to select a language preference of English or French. The sign-in screen allows a user to provide the login credentials. A logged in user can utilize the Portal features available to the user.

The system has several general features that the Portal provides to facilitate the user to utilize the Portal functionality.

- There are hover messages to provide basic information, for almost every data entry or selection that a user can make.
- The symbol is available for data fields that a user can enter, which provides a help message, that gives additional information.
- The system also provides links to ESG informational website pages for detailed help/information where appropriate.
- There are intuitive screen navigation options such as SUBMIT, CANCEL, CONTINUE, GO TO ACCOUNTS SEARCH, etc.

2. Portal Features

The Accounts Management Portal has features to allow the registration of new WebTrader (WT) or Power User (PU) accounts for the Electronic Submissions Gateway (ESG). The Accounts Management Portal also has features available based on the type of user, such as a WebTrader (WT) user, a Power User (PU), or a combined Power user + WebTrader (PU+).

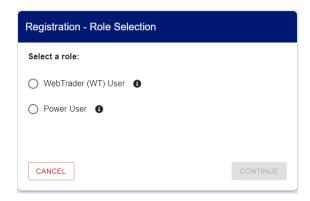
The high-level features of the Portal are:

- 1. Registration: Allows self-registration for both WebTraders and Power Users.
- 2. Account Approval automation: Portal automates account approval process according to FDA business rules.
- 3. Self-serve: Allows self-service such as forgot password, update profile, change password, update certificates, and manage company accounts, etc.
- 4. Submission Search: Allows for submission status search.

2.1. Registration

The Accounts Management Portal allows new Industry users to register for Electronic Submissions Gateway (ESG) accounts. This includes self-registration for both WebTraders and Power Users. An initial screen allows the user to select a language preference of English or French. The sign-in screen allows a user to provide the login credentials. This screen also provides links to initiate a new Account Registration.

A new user is allowed to select the role for the user account, WebTrader or Power user.

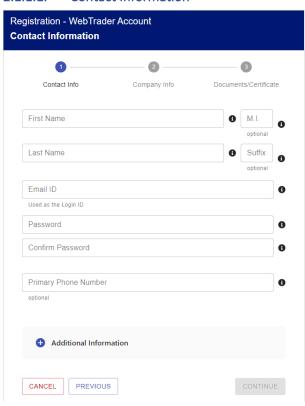


Depending on the role selected, the user is required to provide certain information for the Registration of an ESG Account via the Accounts Management Portal. This includes Profile information, Company information, and documents such as Non-Repudiation Letter, Authorization Letter (optional) and signing Certificate.

2.1.1. WebTrader User Account Registration

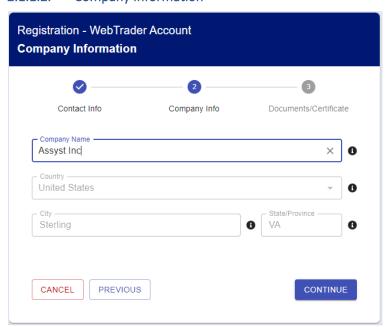
A WebTrader user is required to provide Contact information, Company information, and documents such as Non-Repudiation Letter, Authorization Letter (optional) and signing Certificate, for a new account registration.

2.1.1.1. Contact Information



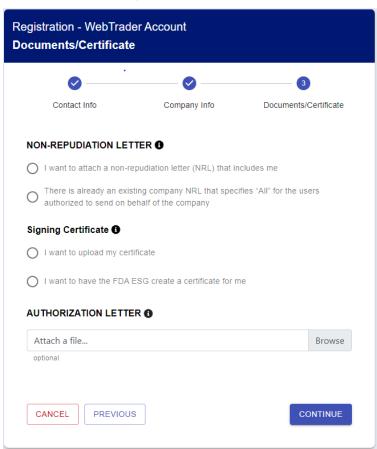
Enter the required data fields. If Secondary user contact information is to be entered, click on the '+' sign for Additional Information. After entering all the data, select CONTINUE. The Company Information screen is displayed next. **Tip**: Always use a strong password and do not share your password.

2.1.1.2. Company Information



Select the Company Name from the dropdown list or enter a new Company Name. If you enter a new Company Name, you must also provide the Country, City and State information for the Company. Then select CONTINUE. The Documents/Certificate screen is displayed next. **Tip**: Start typing a company name to narrow the selection list.

2.1.1.3. Documents/Certificate Information

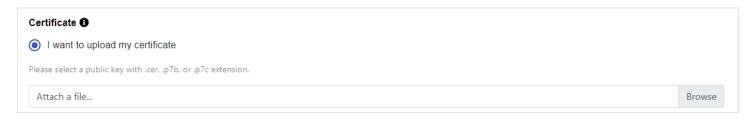


For the Non-Repudiation Letter, you can select the option, 'I want to attach a non-repudiation letter (NRL) that includes me', which will allow you to browse and upload a file for the Non-Repudiation letter.



Or you can select the option, 'There is already an existing company NRL that specifies "All" for the users authorized to send on behalf of the company'.

For the Certificate, you can select the option, 'I want to upload my certificate', which will allow you to browse and upload a file for the Certificate.



Or you can select the option, 'I want to have the FDA ESG create a certificate for me'. If you select this option for the certificate, the system displays a pop-up screen for Create a Certificate Password, to allow you to provide a Certificate password, Re-enter certificate password, and select "SUBMIT". The system will allow you to download the Certificate file. **Tip**: Be sure to note and verify the location where you saved the certificate, you will need this certificate to send submissions.

For the Authorization Letter, if necessary, the system allows you to browse and upload a file for the Authorization letter.



Once you provide all the documents required for the WebTrader Account, select "CONTINUE".

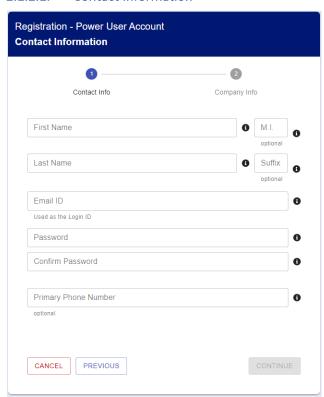
The system will display the Review and Submit screen with all the data values you have entered or selected for Registering the ESG Account, for you to review and confirm, after clicking on checkboxes for certain certifications and selecting SUBMIT. **Tip**: Be sure to read all certifications before you check them off.

The system will accept your request and send you a confirmation email with additional information, once a Pre-Production Account has been created for you.

2.1.2. Power User Account Registration

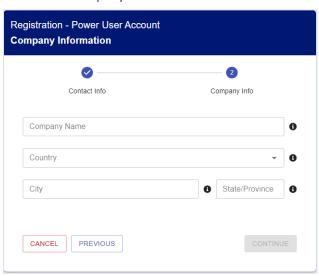
A Power user is only required to Provide Contact and Company information.

2.1.2.1. Contact Information



Enter the required data fields. If Secondary user contact information is to be entered, click on the '+' sign for Additional Information. After entering all the data, select CONTINUE. The Company Information screen is displayed next.

2.1.2.2. Company Information



Select the Company Name from the dropdown list or enter a new Company Name. If you enter a new Company Name, you must also provide the Country, City and State information for the Company. Then select CONTINUE. **Tip**: start typing a company name to narrow the selection list.

The system will display a screen with all the data values you have entered or selected for Registering the ESG Account, for you to review and confirm, after clicking on checkboxes for certain certifications and selecting SUBMIT. **Tip**: Be sure to read all certifications before you check them off.

The system will accept your request and send you a confirmation email with additional information, once your request has been approved.

2.2. Forgot User ID or Password

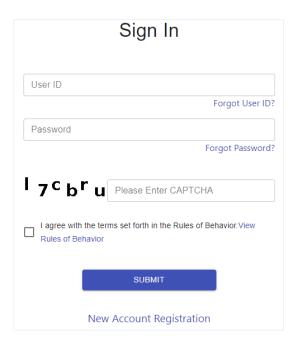
The Portal provides Self-Serve Capabilities to the user for

- Forgot Password
- Forgot User ID

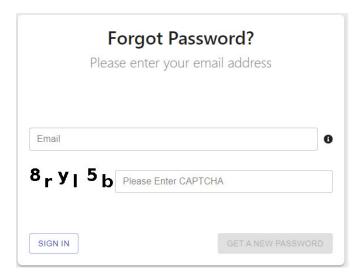
2.2.1. Forgot Password

If a user forgot the password for the account, the user can initiate a password reset.

From the Portal login screen, select "Forgot Password?"



The system shall display the Forgot Password screen.



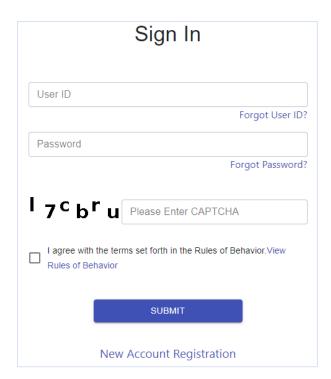
Enter your Email address and enter the CAPTCHA displayed. Then click on "GET A NEW PASSWORD".

The system shall send an email to the user, with a temporary password valid for 15 minutes only. When the user logs in with temporary password the system shall display the Reset Password screen for the user to enter the temporary password, the new password and confirm the new password. This will complete the password update.

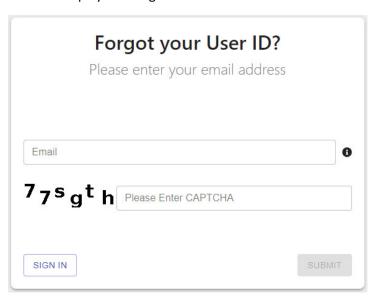
2.2.2. Forgot User ID

If a user forgot the User ID for the account, the user can request the system to provide it.

From the Portal login screen, select "Forgot User ID?"



The system shall display the Forgot User ID screen.



Enter your Email address and enter the CAPTCHA displayed. Then click on "SUBMIT".

The system shall send an email to the user, with the User ID. The user can then go to the Portal login screen and log into the Portal.

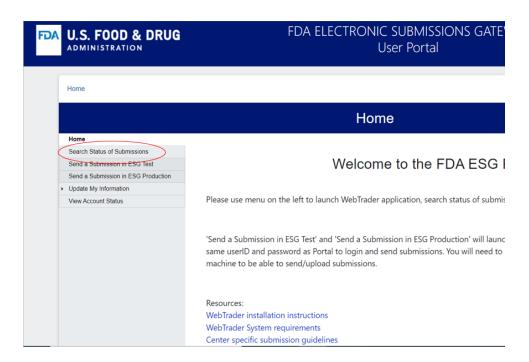
2.3. Features for WebTrader Users

The Accounts Management Portal provides the following features for the WebTrader (WT) user:

- Search Status of Submissions
- Send a Submission in ESG Test
- Send a Submission in ESG Production
- Update Profile
- Update Password
- Upload New Non-Repudiation Letter
- Upload New Authorization Letter
- Upload New Certificate
- Request a Power User Account
- View Account Status

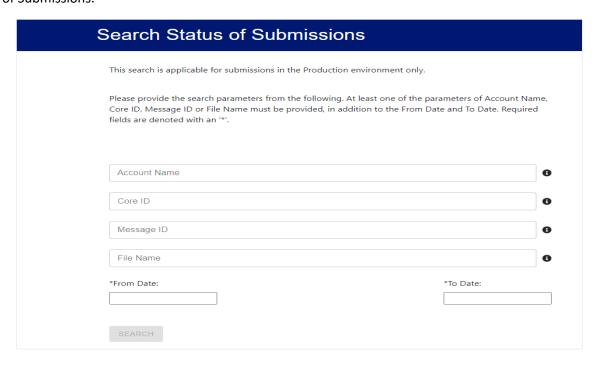
2.3.1. Search Status of Submissions

A WT user can search for the status of own submissions to ESG.



Once the WT user logs in, the WT Home page is displayed. From the menu on the left side, select "Search Status of Submissions".

The Search Status of Submissions screen is displayed, to allow you to enter the selection parameters for the Search Status of Submissions.

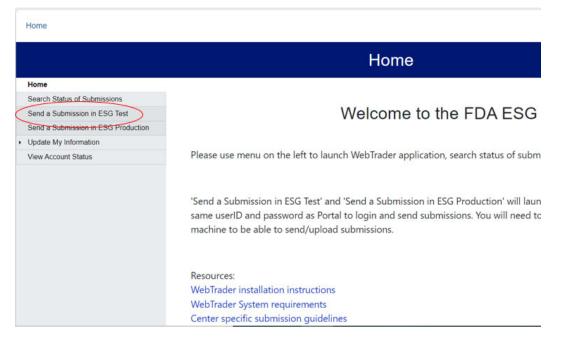


Enter at least one of the parameters of Core ID, Message ID, or File Name, in addition to the From Date and To Date. Core ID and Message ID must be entered as exact values. A full or partial File Name may be entered. The From Date and To Date are required fields. Then select "SEARCH". The system will display the Submissions sent by the WT user to ESG Production, if there are any for the selection parameters.

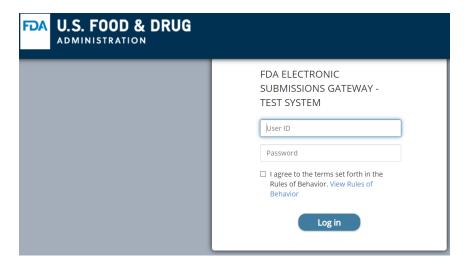
2.3.2. Send a Submission in ESG Test

A WT user can launch the WebTrader for ESG Test in a new window from the Portal.

Once the WT user logs in, the WT Home page is displayed. From the menu on the left side, select "Send a Submission in ESG Test".



The system launches the WebTrader for ESG Test in a new window, as shown in the figure below:

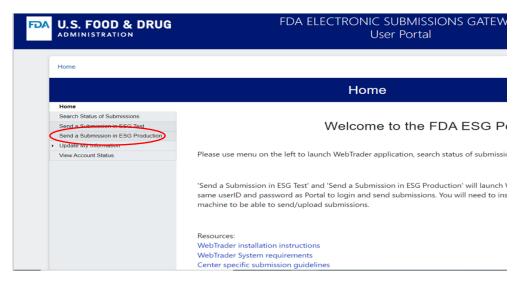


Log into the WebTrader for the FDA Electronic Submissions Gateway – Test System using the same user ID and password as the Portal. **Tip**: Do not make any changes to your profile in the WebTrader system.

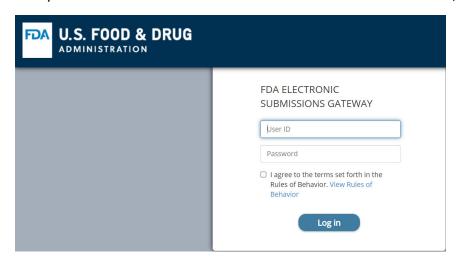
2.3.3. Send a Submission in ESG Production

A WT user can launch the WebTrader for ESG Production in a new window from the Portal.

Once the WT user logs in, the WT Home page is displayed. From the menu on the left side, select "Send a Submission in ESG Production".



The system launches the WebTrader for ESG Production in a new window, as shown in the figure below:

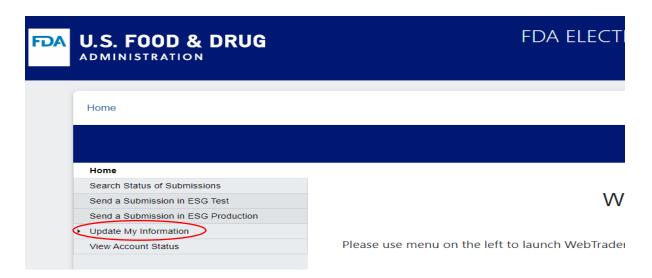


Log into the WebTrader for the FDA Electronic Submissions Gateway using the same user ID and password as the Portal.

2.3.4. Update Profile

A WT user can update certain fields of own profile on the Portal.

Once the WT user logs in, the WT Home page is displayed. From the menu on the left side, select "Update My Information" to expand the menu.

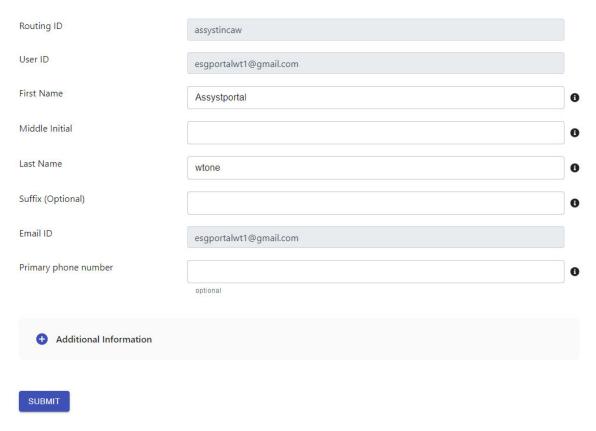


From the expanded menu displayed, select "Update Profile".

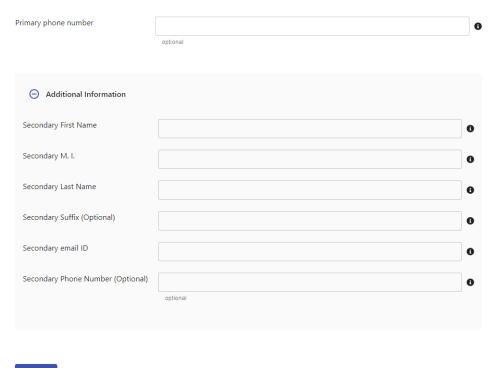


The screen for Update Profile is then displayed, with the current data for the user's profile.

Update Profile



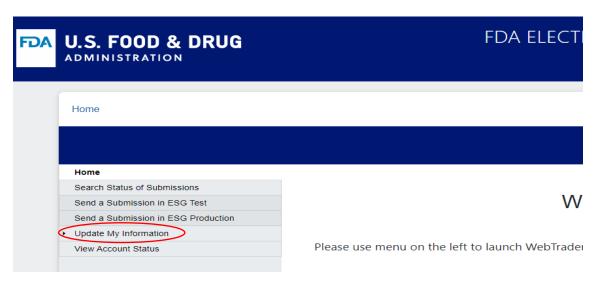
You can update the First Name, Middle Initial, Last Name, Suffix and the Phone Number, as desired, and select the "SUBMIT" button. You can also click on the toggle switch "+", to view and update Additional Information, which includes the Secondary Contact's First Name, Middle Initial, Last Name, Suffix, email ID and the Phone Number, if required.



2.3.5. Update Password

A WT user can update the password on the Portal.

Once the WT user logs in, the WT Home page is displayed. From the menu on the left side, select "Update My Information" to expand the menu.



From the expanded menu displayed, select "Update Password".



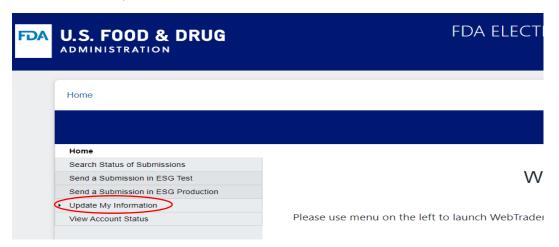
The Update Password screen is displayed. You can update the password by entering the current password, a new password, re-entering the new password and selecting "SUBMIT".



2.3.6. Upload New Non-Repudiation Letter

A WT user can upload a New Non-Repudiation Letter on the Portal.

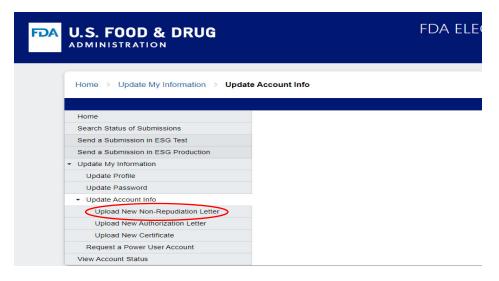
Once the WT user logs in, the WT Home page is displayed. From the menu on the left side, select "Update My Information" to expand the menu.



From the expanded menu displayed, select "Update Account Info", to expand the menu further.



From the further expanded menu displayed, select "Upload New Non-Repudiation Letter".



The Upload New Non-Repudiation Letter screen is displayed, including any existing letters. Click on "Browse", to select the file for the New Non-Repudiation Letter from your computer, that needs to be uploaded. Select the checkbox for "I hereby certify that this letter includes me". Then select "SUBMIT".



2.3.7. Upload New Authorization Letter

A WT user can upload a New Authorization Letter on the Portal.

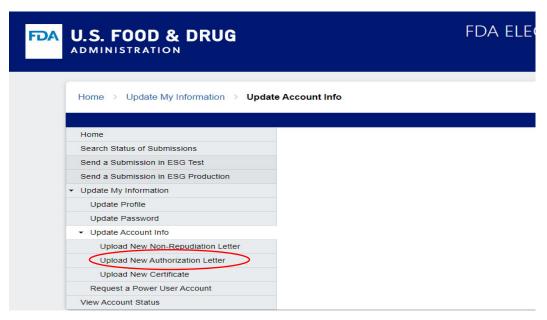
Once the WT user logs in, the WT Home page is displayed. From the menu on the left side, select "Update My Information" to expand the menu.



From the expanded menu displayed, select "Update Account Info", to expand the menu further.



From the further expanded menu displayed, select "Upload New Authorization Letter".



The Upload New Authorization Letter screen is displayed, including any existing letters. Select "Browse", to select the file for the New Authorization Letter from your computer, that needs to be uploaded. Select the checkbox for "I hereby certify that this letter includes me". Then select "SUBMIT".



2.3.8. Upload New Certificate

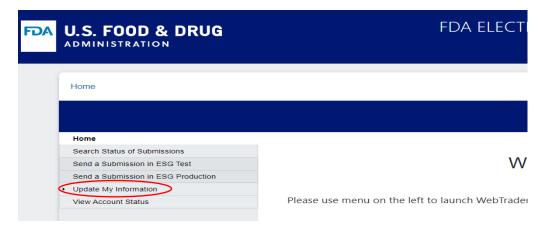
A WT user can upload a New Certificate on the Portal.

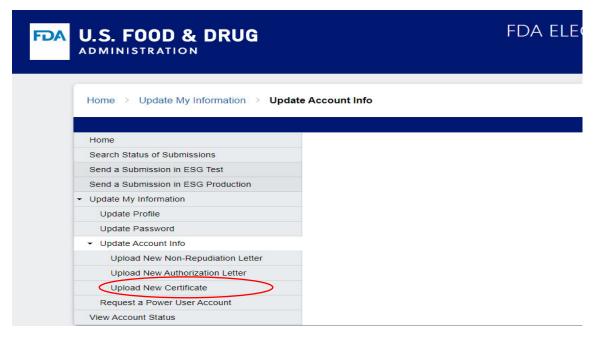
Once the WT user logs in, the WT Home page is displayed. From the menu on the left side, select "Update My Information" to expand the menu.

From the expanded menu displayed, select "Update Account Info", to expand the menu further.

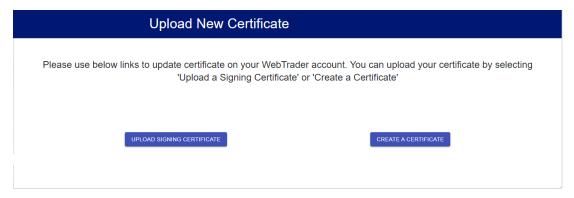


From the further expanded menu displayed, select "Upload New Certificate".



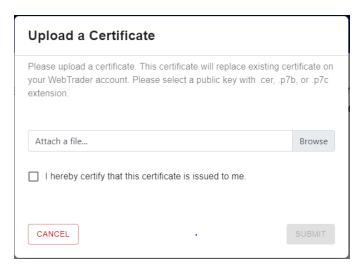


The Upload New Certificate screen is displayed.

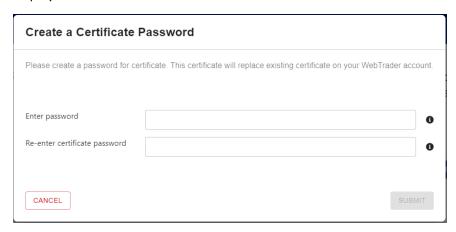


You can upload your certificate by selecting "UPLOAD SIGNING CERTIFICATE" or "CREATE A CERTIFICATE".

If you already have a new certificate to upload, select "UPLOAD SIGNING CERTIFICATE". A pop-up window is displayed for "Upload a Certificate". Click on "Browse", to select the file for the New Certificate from your computer, that needs to be uploaded. Select the checkbox for "I hereby certify that this certificate is issued to me". Then select "SUBMIT".



If you would like ESG to create a new certificate for you, select "CREATE A CERTIFICATE". A pop-up window is displayed for "Create a Certificate Password".

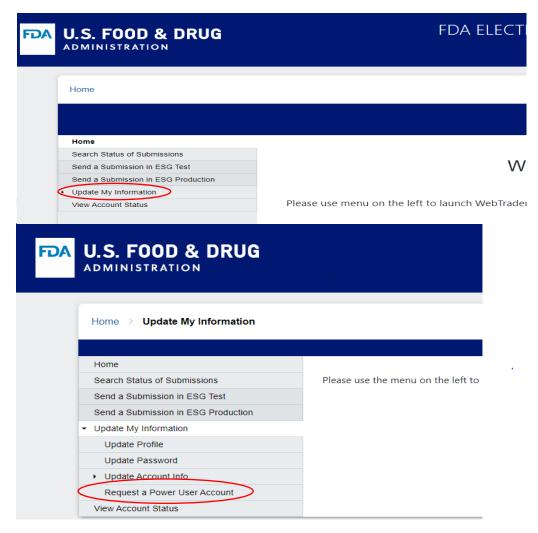


Enter a password for the new certificate. Re-enter the password for confirmation. Then select "SUBMIT".

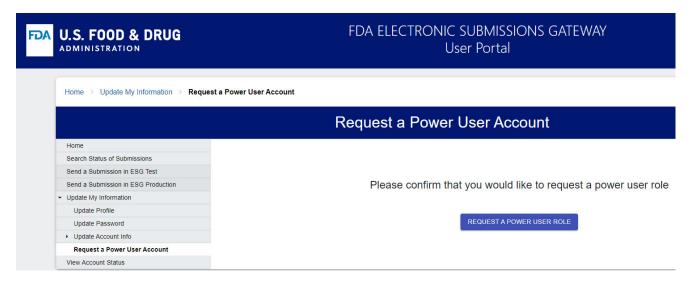
2.3.9. Request a Power User Account

A WT user can request a Power User Account on the Portal.

Once the WT user logs in, the WT Home page is displayed. From the menu on the left side, select "Update My Information" to expand the menu.



The Request a Power User Account screen is displayed.



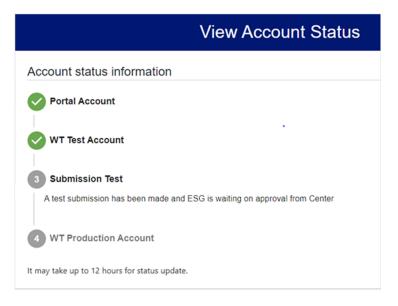
You can confirm your request for a Power User Account by selecting "REQUEST A POWER USER ROLE". **Tip**: An FDA ESG Admin needs to approve the Power User role, please wait for approval email before logging in to validate Power User features.

2.3.10. View Account Status

A WT user can view the status of own Account. This is useful when the WT user first registers on the Portal.



Once the WT user logs in, the WT Home page is displayed. From the menu on the left side, select "View Account Status".



The View Account Status screen is displayed, with the status of the WT Account.

2.4. Features for Power Users

The Accounts Management Portal provides the following features for the Power user:

- Search Status of Submissions
- Update Profile
- Update Password
- Update Company Profile
- Upload New Non-Repudiation Letter for Company
- Upload New Authorization Letter for Company
- Search and Update Company Accounts
- Upload a Non-Repudiation Letter for selected Account
- Upload an Authorization Letter for selected Account
- Upload a new Certificate for selected Account
- Request a WebTrader Account
- View Account Status

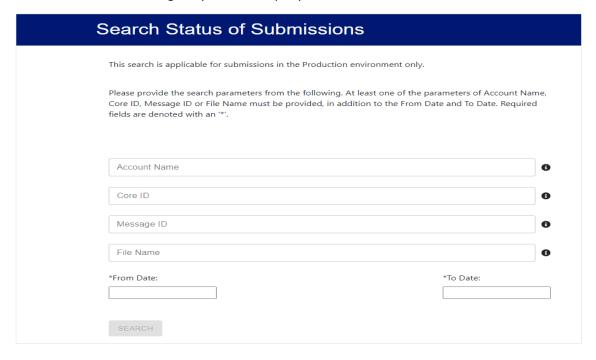
2.4.1. Search Status of Submissions

A Power user can search for the status of submissions to ESG from any WT user of own company.

Once the Power user logs in, the Power Home page is displayed. From the menu on the left side, select "Search Status of Submissions".



The Search Status of Submissions screen is displayed, to allow you to enter the selection parameters for the Search Status of Submissions made through any of the company accounts.



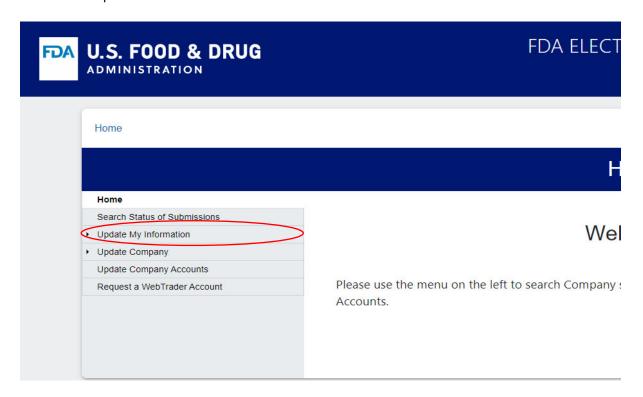
Enter at least one of the parameters of Account Name, Core ID, Message ID, or File Name, in addition to the From Date and To Date. Core ID and Message ID must be entered as exact values. A full or partial File Name may be entered. The From Date and To Date are required fields. Then select "SEARCH".

The system will display the Submissions sent by company WT user(s) of the specific Company to ESG Production, if there are any for the selection parameters.

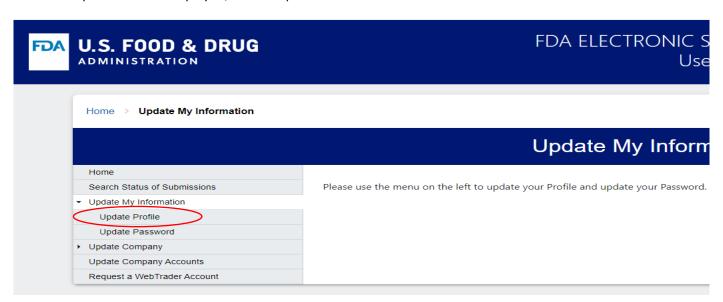
2.4.2. Update Profile

A Power user can update certain fields of own profile on the Portal.

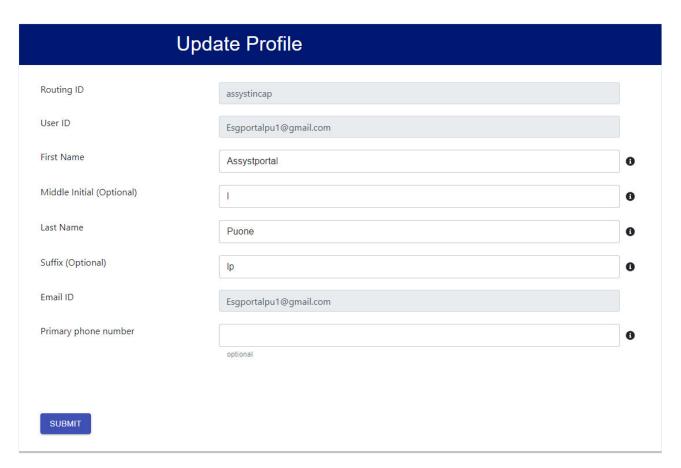
Once the Power user logs in, the Power user Home page is displayed. From the menu on the left side, select "Update My Information" to expand the menu.



From the expanded menu displayed, select "Update Profile".



The screen for Update Profile is then displayed, with the current data for the user's profile.

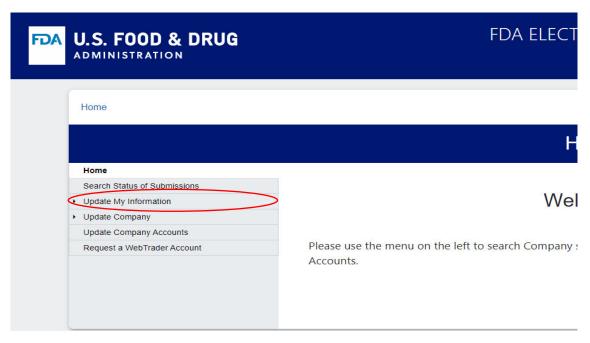


You can update the First Name, Middle Initial, Last Name, Suffix and the Phone Number, as desired, and select the "SUBMIT" button.

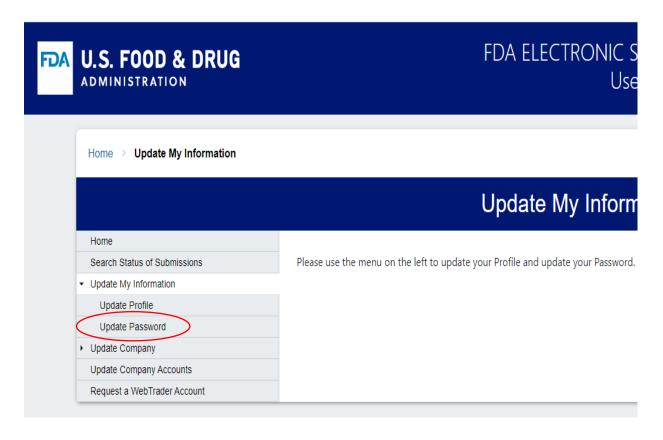
2.4.3. Update Password

A Power user can update the password on the Portal.

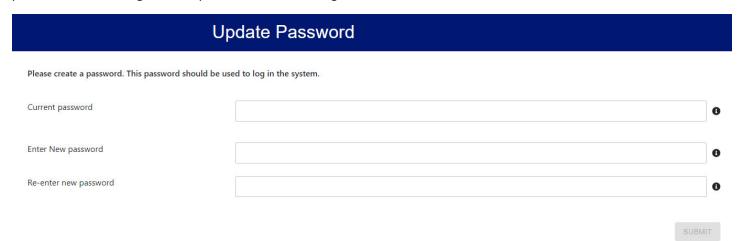
Once the Power user logs in, the Power user Home page is displayed. From the menu on the left side, select "Update My Information" to expand the menu.



From the expanded menu displayed, select "Update Password".



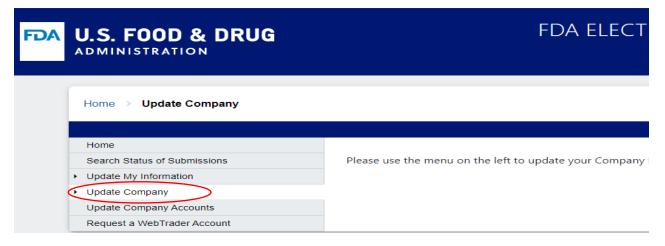
The Update Password screen is displayed. You can update the password by entering the current password, a new password, re-entering the new password and selecting "SUBMIT".



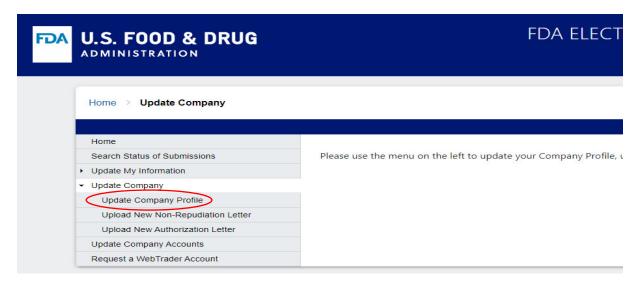
2.4.4. Update Company Profile

A Power user can update the profile of own company on the Portal.

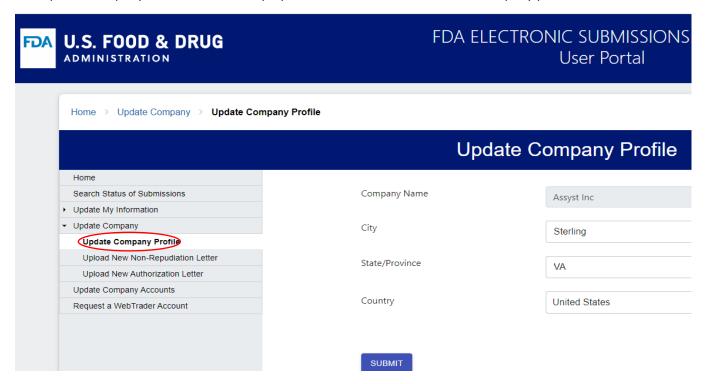
Once the Power user logs in, the Power user Home page is displayed. From the menu on the left side, select "Update Company" to expand the menu.



From the expanded menu displayed, select "Update Company Profile".



The Update Company Profile screen is displayed with the current data for the company profile.

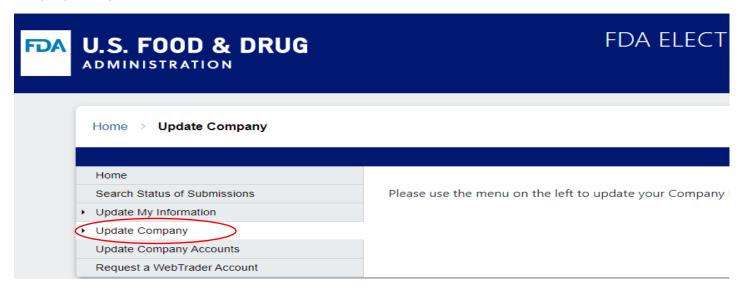


You can update the City, State/Province and Country as desired, and select the "SUBMIT" button.

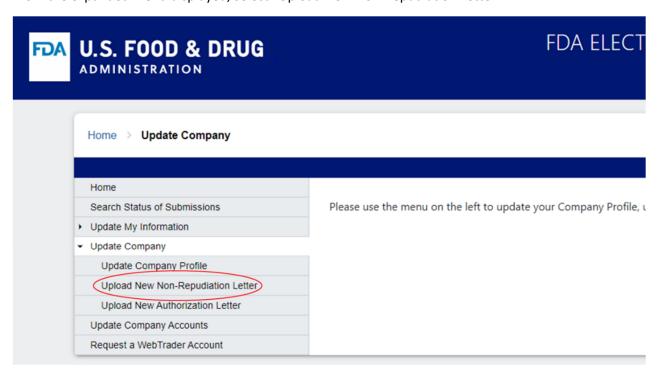
2.4.5. Upload New Non-Repudiation Letter for Company

A Power user can upload a New Non-Repudiation Letter for own Company on the Portal.

Once the Power user logs in, the Power user Home page is displayed. From the menu on the left side, select "Update Company" to expand the menu.



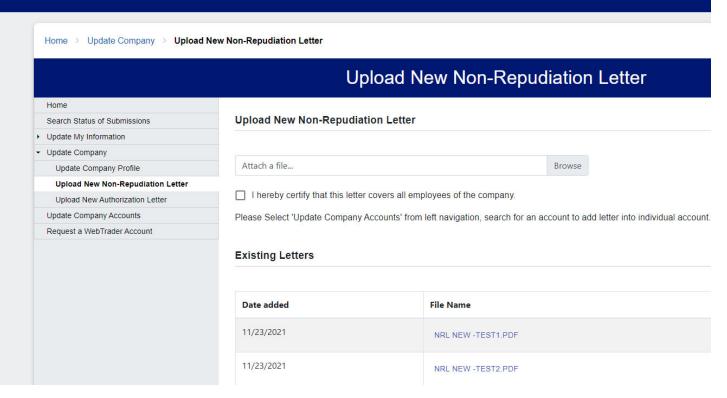
From the expanded menu displayed, select "Upload New Non-Repudiation Letter".



The Upload New Non-Repudiation Letter screen is displayed with existing letters for the company, along with the ability to select and upload a new Non-Repudiation Letter.



FDA ELECTRONIC SUBMISSIONS GATEWA' User Portal

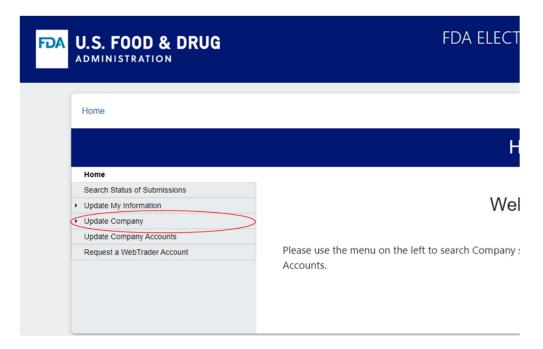


You can browse and select a file from your computer for the New Non-Repudiation Letter and then select the "SUBMIT" button.

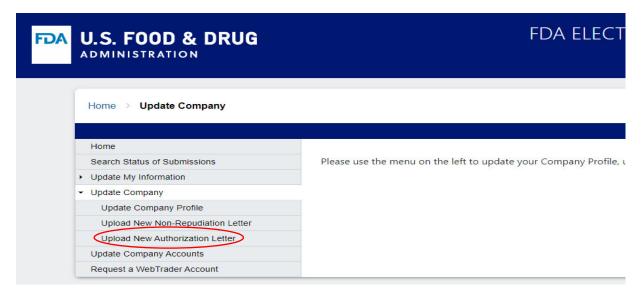
2.4.6. Upload New Authorization Letter for Company

A Power user can upload a New Authorization Letter for own Company on the Portal.

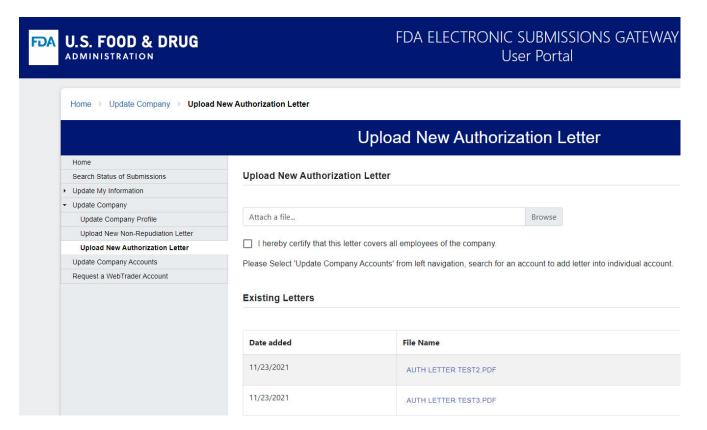
Once the Power user logs in, the Power user Home page is displayed. From the menu on the left side, select "Update Company" to expand the menu.



From the expanded menu displayed, select "Upload New Authorization Letter".



The Upload New Authorization Letter screen is displayed with existing letters for the company, along with the ability to select and upload a new Authorization Letter.

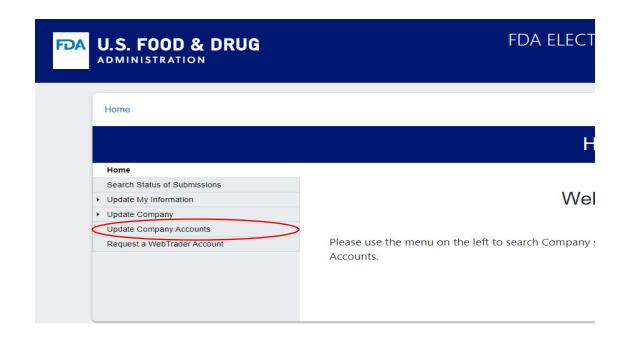


You can browse and select a file from your computer for the New Authorization Letter using the "Browse" button, and then select the "SUBMIT" button.

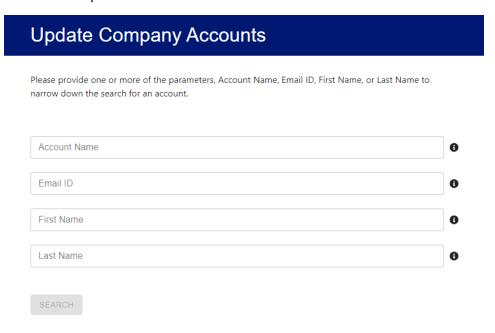
2.4.7. Search and Update Company Accounts

A Power user can search and update Accounts for own Company on the Portal.

Once the Power user logs in, the Power user Home page is displayed. From the menu on the left side, select "Update Company Accounts".

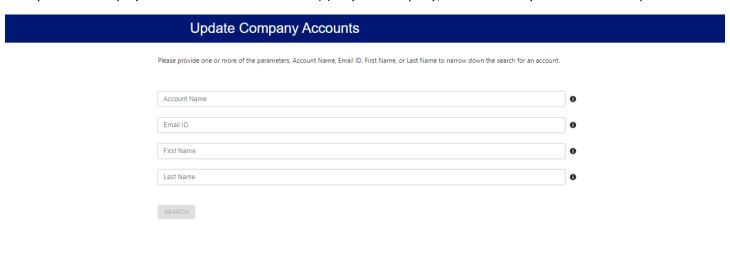


The Update Company Accounts screen is displayed, to allow you to enter the selection parameters to search for the Account that is to be updated.



Enter at least one of the parameters of Account Name, Email ID, First Name, or Last Name. Full or partial parameter values may be entered. Then select "SEARCH".

The system will display the ESG Accounts of WT user(s) of your Company, if there are any for the selection parameters.



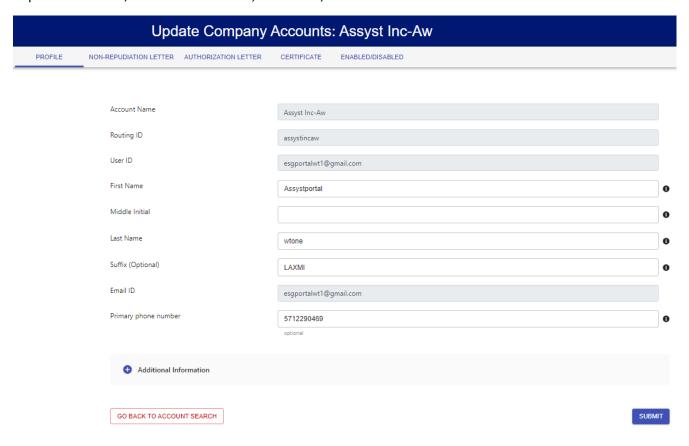
*Please click on the row to select an account to edit.



Click on a row to select an Account to view or edit.

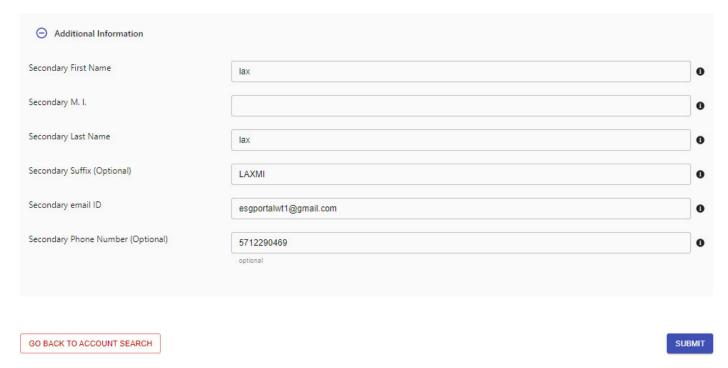
2.4.7.1. Update Profile of a Company Account

The screen for Update Company Accounts with the Profile tab is then displayed, with the current data for the selected user's profile. There are also other tabs available on the screen that you can select, for viewing or updating Non-Repudiation Letter, Authorization Letter, Certificate, or to Disable an Account.



You can update the First Name, Middle Initial, Last Name, Suffix and the Phone Number, as desired, and select the "SUBMIT" button. You can also click on the toggle switch "+", to view and update Additional Information, which includes the Secondary Contact's First Name, Middle Initial, Last Name, Suffix, email ID and the Phone Number, if required.

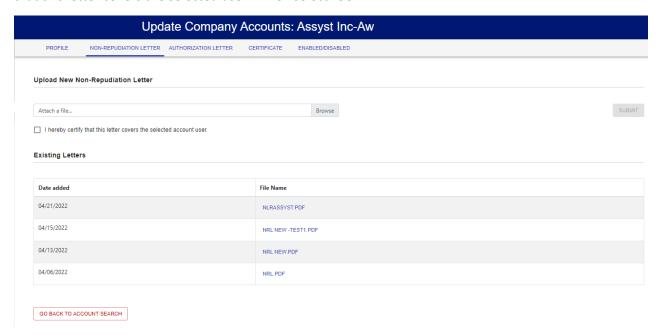
You can select the "GO BACK TO ACCOUNT SEARCH" button to select another Account to view or update.



2.4.7.2. Upload Non-Repudiation Letter for a Company Account

Once the specific Account is selected from the displayed list of the chosen Accounts for the Company, the screen for Update Company Accounts with the Profile tab is then displayed, with the current data for the selected user's profile. Select the tab for Non-Repudiation Letter.

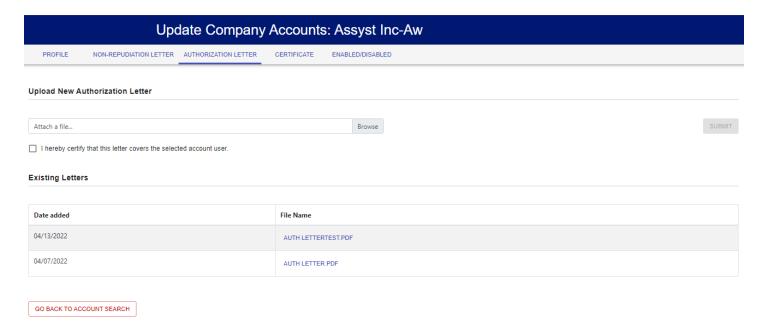
The screen for Update Company Accounts with the Non-Repudiation Letter tab is then displayed, with the current data for the selected user. Any existing letters for the Account are also displayed. Click on "Browse", to select the file for the New Non-Repudiation Letter from your computer, that needs to be uploaded. Select the checkbox for "I hereby certify that this letter covers the selected user". Then select "SUBMIT".



2.4.7.3. Upload Authorization Letter for a Company Account

Once the specific Account is selected from the displayed list of the chosen Accounts for the Company, the screen for Update Company Accounts with the Profile tab is then displayed, with the current data for the selected user's profile. Select the tab for Authorization Letter.

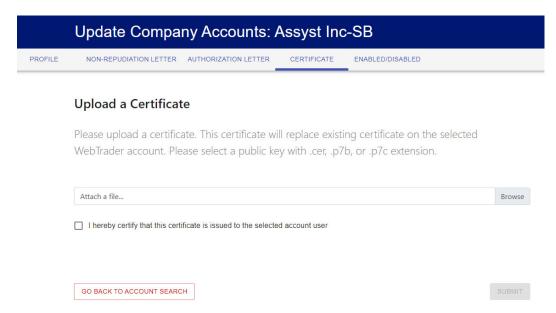
The screen for Update Company Accounts with the Authorization Letter tab is then displayed, with the current data for the selected user. Any existing letters for the Account are also displayed. Click on "Browse", to select the file for the New Non-Repudiation Letter from your computer, that needs to be uploaded. Select the checkbox for "I hereby certify that this letter covers the selected user". Then select "SUBMIT".



2.4.7.4. Upload Certificate for a Company Account

Once the specific Account is selected from the displayed list of the chosen Accounts for the Company, the screen for Update Company Accounts with the Profile tab is then displayed, with the current data for the selected user's profile. Select the tab for Certificate.

The screen for Update Company Accounts with the Certificate tab is then displayed. Click on "Browse", to select the file for the New Certificate from your computer, that needs to be uploaded. Select the checkbox for "I hereby certify that this certificate is issued to the selected user". Then select "SUBMIT".

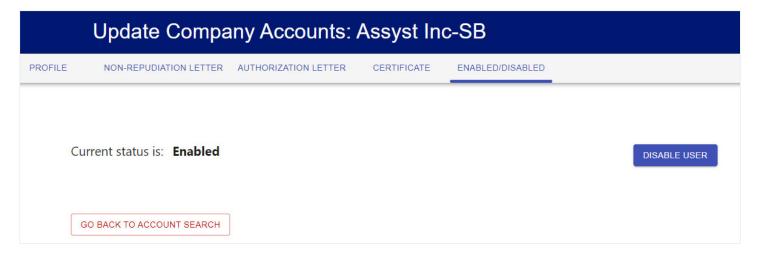


2.4.7.5. Update Status of a Company Account

Once the specific Account is selected from the displayed list of the chosen Accounts for the Company, the screen for Update Company Accounts with the Profile tab is then displayed, with the current data for the selected user's profile. Select the tab for Enabled/Disabled.

The screen for Update Company Accounts with the Enabled/Disabled tab is then displayed, with the status of the selected Account. If an Account is Enabled, you can Disable the Account by selecting "DISABLE USER". Otherwise, select "GO BACK TO ACCOUNT SEARCH", or select a menu option from the Navigation options on the left.

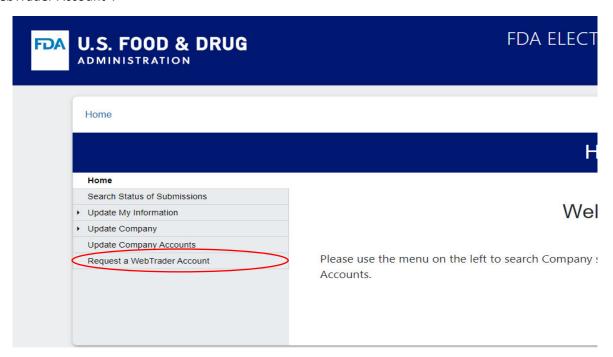
Note: The enabling of Accounts is restricted for the use of ESG FDA Admin from the ESG Help Desk.



2.4.8. Request a WebTrader Account

A Power user can Request a WebTrader Account for own Company on the Portal.

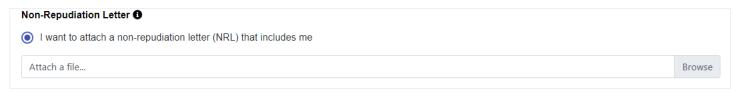
Once the Power user logs in, the Power user Home page is displayed. From the menu on the left side, select "Request a WebTrader Account".



The screen for Request a WebTrader Account Screen is displayed. You can provide the documents required for the WebTrader Account.

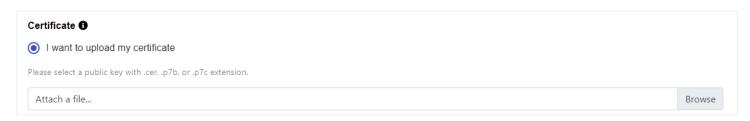
Non-Repudiation Letter ○ I want to attach a non-repudiation letter (NRL) that includes me ○ There is already an existing company NRL that specifies "AII" for the users authorized to send on behalf of the company Certificate ○ I want to upload my certificate ○ I want to have the FDA ESG create a certificate for me Authorization Letter Attach a file... Optional Browse

For the Non-Repudiation Letter, you can select the option, 'I want to attach a non-repudiation letter (NRL) that includes me', which will allow you to browse and upload a file for the Non-Repudiation letter.



Or you can select the option, 'There is already an existing company NRL that specifies "All" for the users authorized to send on behalf of the company'.

For the Certificate, you can select the option, 'I want to upload my certificate', which will allow you to browse and upload a file for the Certificate.



Or you can select the option, 'I want to have the FDA ESG create a certificate for me'. If you select this option for the certificate, the system displays a pop-up screen for Create a Certificate Password, to allow you to provide a Certificate password, Re-enter certificate password, and select "SUBMIT". The system will allow you to download the Certificate file.

For the Authorization Letter, if necessary, the system allows you to browse and upload a file for the Authorization letter.



Once you provide all the documents required for the WebTrader Account, you can select the checkbox for "I hereby certify that the information I have provided is true and I am authorized to register with the FDA". Then select "SUBMIT".

The system will accept your request and send you a confirmation email with additional information, once a Pre-Production Account has been created for you.

2.5. Features for a Power User+ (PU+)

A Power User+ can perform features of a PU as well as a WT.

The Accounts Management Portal provides the following features for a combined Power user+:

- Search Status of Submissions
- Send a Submission in ESG Test
- Send a Submission in ESG Production
- Update Profile
- Update Password
- Upload a new Non-Repudiation Letter (for own Account)
- Upload a new Authorization Letter (for own Account)
- Upload a new Certificate (for own Account)
- Update Company Profile
- Upload a Non-Repudiation Letter for Company
- Upload an Authorization Letter for Company
- Search and Update Company Accounts
- Upload a Non-Repudiation Letter for selected Account
- Upload an Authorization Letter for selected Account
- Upload a new Certificate for selected Account
- View Account Status

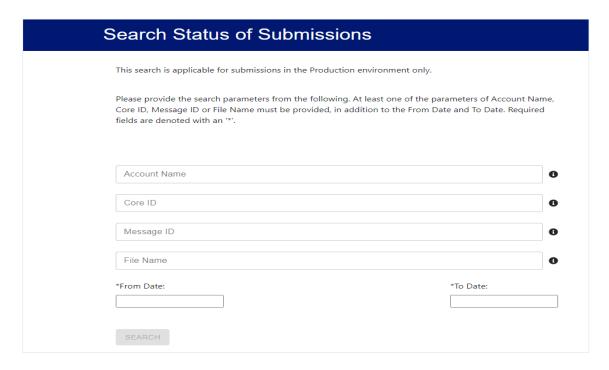
2.5.1. Search Status of Submissions

A Power User+ can search for the status of submissions to ESG from any WT user of own company.

Once the Power User+ logs in, the appropriate Home page is displayed. From the menu on the left side, select "Search Status of Submissions".



The Search Status of Submissions screen is displayed, to allow you to enter the selection parameters for the Search Status of Submissions.



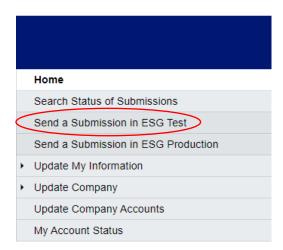
Enter at least one of the parameters of Account Name, Core ID, Message ID, or File Name, in addition to the From Date and To Date. Core ID and Message ID must be entered as exact values. A full or partial File Name may be entered. The From Date and To Date are required fields. Then select "SEARCH".

The system will display the Submissions sent by WT user(s) of the specific Company to ESG Production, if there are any for the selection parameters.

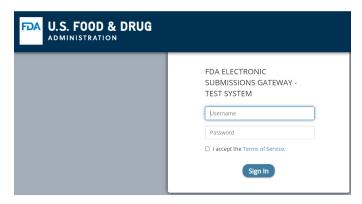
2.5.2. Send a Submission in ESG Test

A Power User+ can launch the WebTrader for ESG Test in a new window from the Portal.

Once the Power User+ logs in, the Power User+ Home page is displayed. From the menu on the left side, select "Send a Submission in ESG Test".



The system launches the WebTrader for ESG Test in a new window, as shown in the figure below:



Log into the WebTrader for the FDA Electronic Submissions Gateway – Test System using the same user ID and password as the Portal.

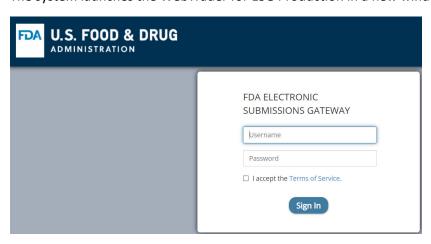
2.5.3. Send a Submission in ESG Production

A Power User+ can launch the WebTrader for ESG Production in a new window from the Portal.

Once the Power User+ logs in, the Power User+ Home page is displayed. From the menu on the left side, select "Send a Submission in ESG Production".



The system launches the WebTrader for ESG Production in a new window, as shown in the figure below:

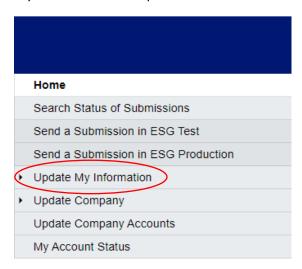


Log into the WebTrader for the FDA Electronic Submissions Gateway using the same user ID and password as the Portal.

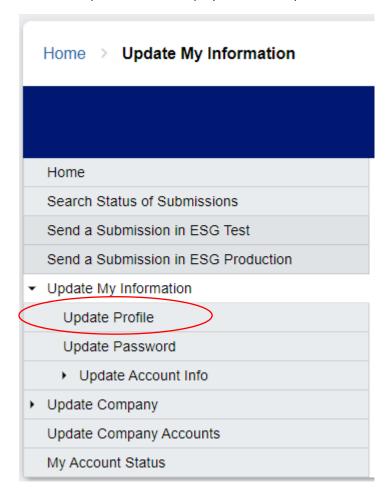
2.5.4. Update Profile

A Power User+ can update certain fields of own profile on the Portal.

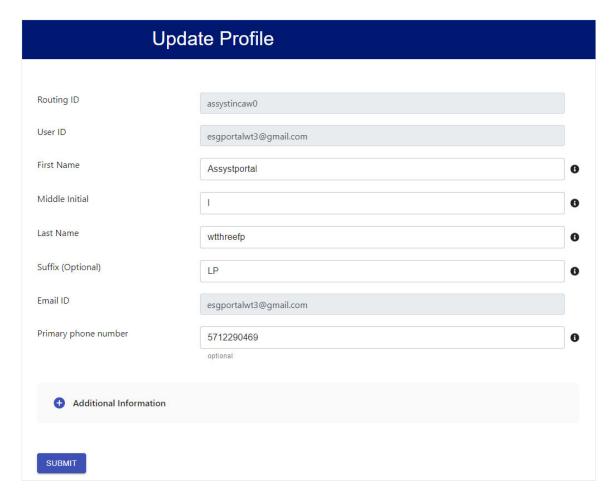
Once the Power User+ logs in, the Power user Home page is displayed. From the menu on the left side, select "Update My Information" to expand the menu.



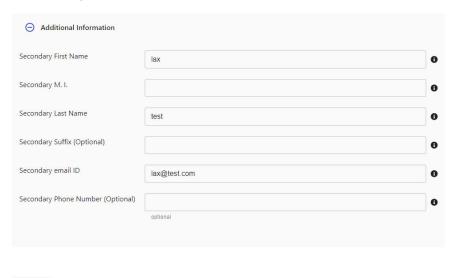
From the expanded menu displayed, select "Update Profile".



The screen for Update Profile is then displayed, with the current data for the user's profile.



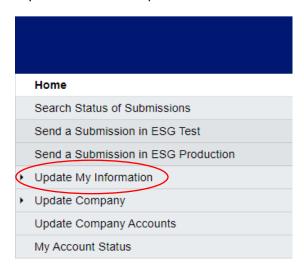
You can update the First Name, Middle Initial, Last Name, Suffix and the Phone Number, as desired, and select the "SUBMIT" button. You can also click on the toggle switch "+", to view and update Additional Information, which includes the Secondary Contact's First Name, Middle Initial, Last Name, Suffix, email ID and the Phone Number, if required.



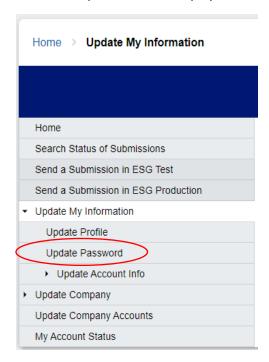
2.5.5. Update Password

A Power User+ can update certain fields of own Password on the Portal.

Once the Power User+ logs in, the Power user Home page is displayed. From the menu on the left side, select "Update My Information" to expand the menu.



From the expanded menu displayed, select "Update Password".

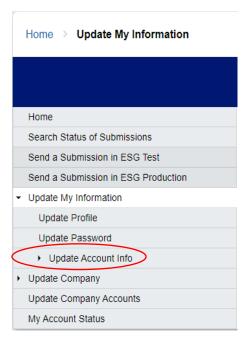


The Update Password screen is displayed. You can update the password by entering the current password, a new password, re-entering the new password and selecting "SUBMIT".

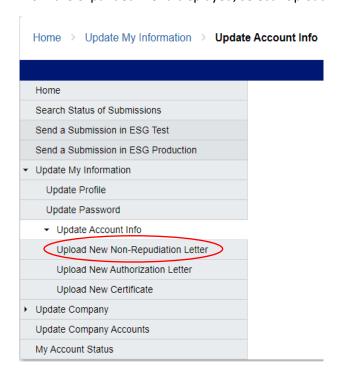
2.5.6. Upload New Non-Repudiation Letter (for own Account)

A Power User+ can upload a New Non-Repudiation Letter for own Account on the Portal.

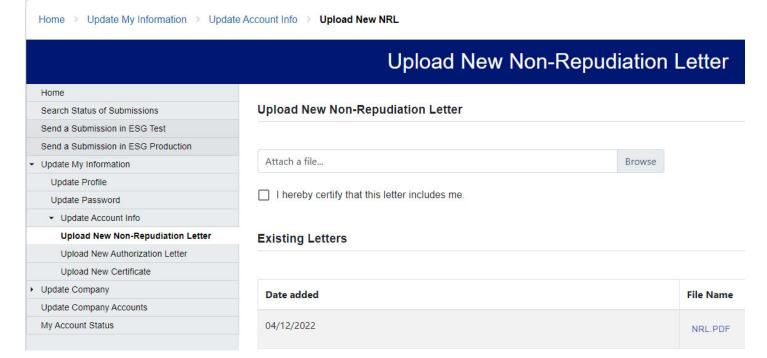
Once the Power user logs in, the Power user Home page is displayed. From the menu on the left side, select "Update Account Info" to expand the menu.



From the expanded menu displayed, select "Upload New Non-Repudiation Letter".



The Upload New Non-Repudiation Letter screen is displayed with existing letters for own account, along with the ability to select and upload a new Non-Repudiation Letter.

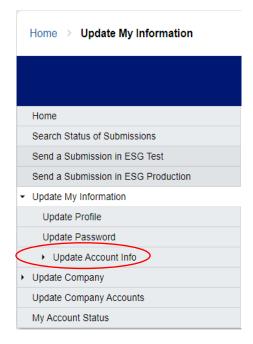


You can browse and select a file from your computer for the New Non-Repudiation Letter using the "Browse" button, and then select the "SUBMIT" button.

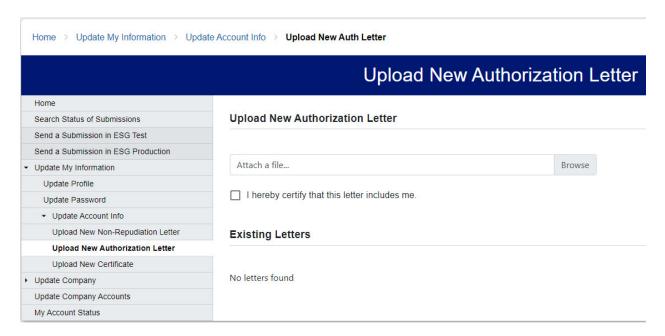
2.5.7. Upload New Authorization Letter (for own Account)

A Power User+ can upload a New Authorization Letter for own Account on the Portal.

Once the Power user logs in, the Power user Home page is displayed. From the menu on the left side, select "Update Account Info" to expand the menu.



From the expanded menu displayed, select "Upload New Authorization Letter".

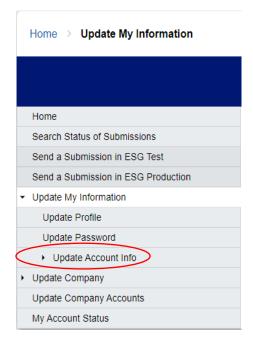


You can browse and select a file from your computer for the New Authorization Letter using the "Browse" button, and then select the "SUBMIT" button.

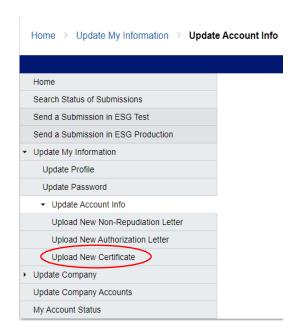
2.5.8. Upload New Certificate (for own Account)

A Power User+ can upload a New Authorization Letter for own Account on the Portal.

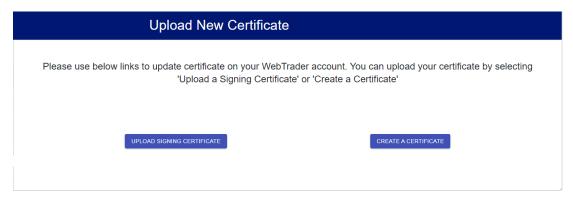
Once the Power user+ logs in, the Power user+ Home page is displayed. From the menu on the left side, select "Update Account Info" to expand the menu.



From the expanded menu displayed, select "Upload New Certificate".

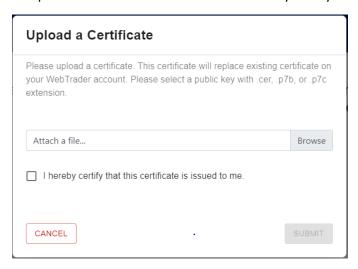


The Upload New Certificate screen is displayed.

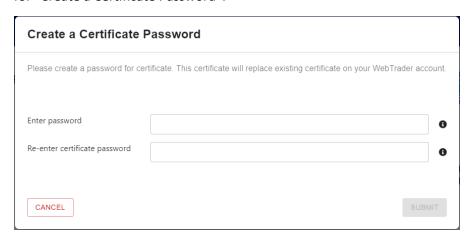


You can upload your certificate by selecting "UPLOAD SIGNING CERTIFICATE" or "CREATE A CERTIFICATE".

If you already have a new certificate to upload, select "UPLOAD SIGNING CERTIFICATE". A pop-up window is displayed for "Upload a Certificate". Click on "Browse", to select the file for the New Certificate from your computer, that needs to be uploaded. Select the checkbox for "I hereby certify that this certificate is issued to me". Then select "SUBMIT".



If you would like ESG to create a new certificate for you, select "CREATE A CERTIFICATE". A pop-up window is displayed for "Create a Certificate Password".



Enter a password for the new certificate. Then re-enter the password for confirmation. Then select "SUBMIT".

2.5.9. Update Company Profile

A Power User+ can update the profile of own company on the Portal.

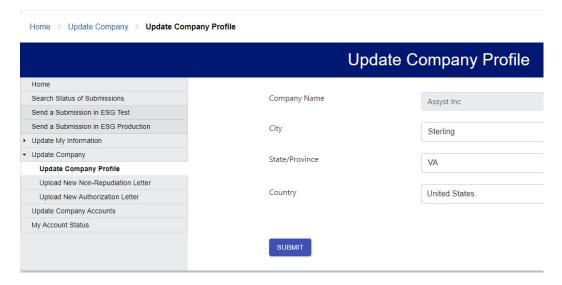
Once the Power user+ logs in, the Power user+ Home page is displayed. From the menu on the left side, select "Update Company" to expand the menu.



From the expanded menu displayed, select "Update Company Profile".



The Update Company Profile screen is displayed with the current data for the company profile.



You can update the City, State/Province and Country as desired, and select the "SUBMIT" button.

2.5.10. Upload New Non-Repudiation Letter for Company

A Power User+ can upload a New Non-Repudiation Letter for own company on the Portal.

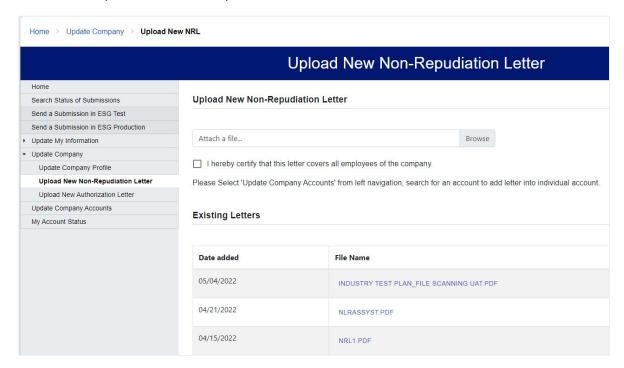
Once the Power user+ logs in, the Power user+ Home page is displayed. From the menu on the left side, select "Update Company" to expand the menu.



From the expanded menu displayed, select "Upload New Non-Repudiation Letter".



The Upload New Non-Repudiation Letter screen is displayed with existing letters for the company, along with the ability to select and upload a new Non-Repudiation Letter.

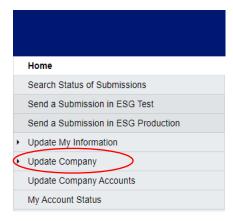


You can browse and select a file from your computer for the New Non-Repudiation Letter and then select the "SUBMIT" button.

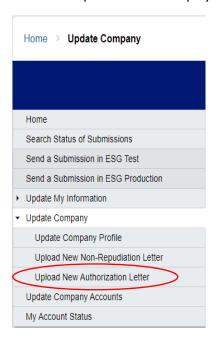
2.5.11. Upload New Authorization Letter for Company

A Power User+ can upload a New Authorization Letter for own company on the Portal.

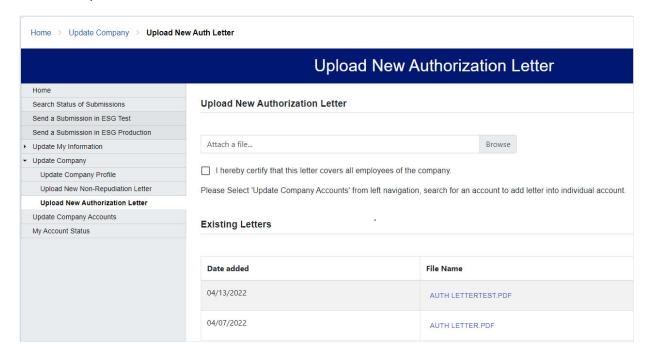
Once the Power user+ logs in, the Power user+ Home page is displayed. From the menu on the left side, select "Update Company" to expand the menu.



From the expanded menu displayed, select "Upload New Authorization Letter".



The Upload New Authorization Letter screen is displayed with existing letters for the company, along with the ability to select and upload a new Authorization Letter.



You can browse and select a file from your computer for the New Authorization Letter using the "Browse" button, and then select the "SUBMIT" button.

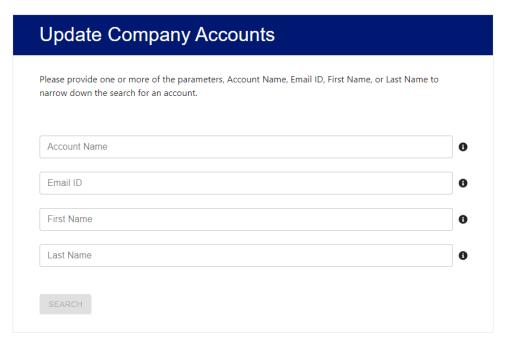
2.5.12. Search and Update Company Accounts

A Power User+ can search and update Accounts for own company on the Portal.

Once the Power user+ logs in, the Power user+ Home page is displayed. From the menu on the left side, select "Update Company Accounts".

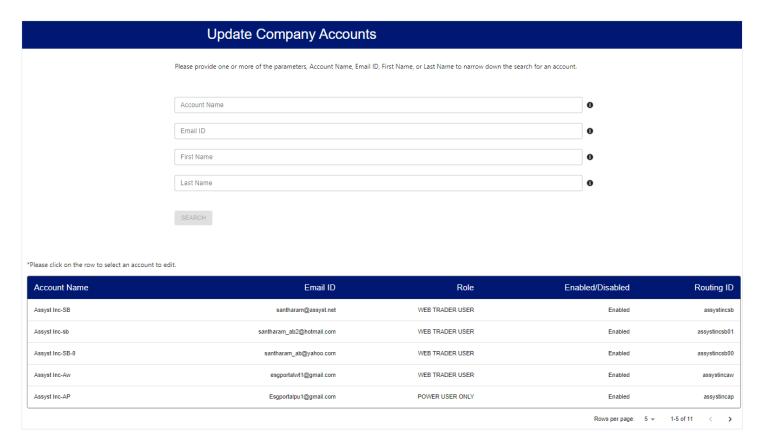


The Update Company Accounts screen is displayed, to allow you to enter the selection parameters to search for the Account that is to be updated.



Enter at least one of the parameters of Account Name, Email ID, First Name, or Last Name. Full or partial parameter values may be entered. Then select "SEARCH".

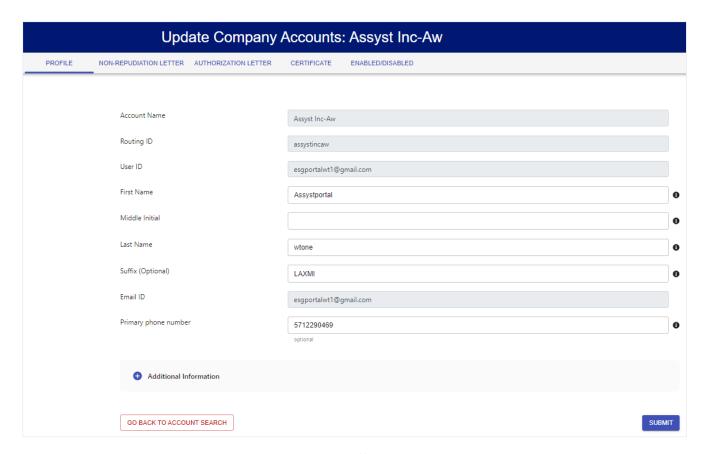
The system will display the ESG Accounts of WT user(s) of your Company, if there are any for the selection parameters.



Click on a row to select an Account to view or edit.

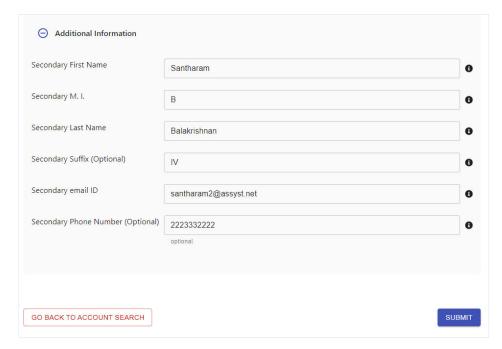
2.5.12.1. Update Profile of a Company Account

The screen for Update Company Accounts with the Profile tab is then displayed, with the current data for the selected user's profile. There are also other tabs available on the screen that you can select, for viewing or updating Non-Repudiation Letter, Authorization Letter, Certificate, or to Disable an Account.



You can update the First Name, Middle Initial, Last Name, Suffix and the Phone Number, as desired, and select the "SUBMIT" button. You can also click on the toggle switch "+", to view and update Additional Information, which includes the Secondary Contact's First Name, Middle Initial, Last Name, Suffix, email ID and the Phone Number, if required.

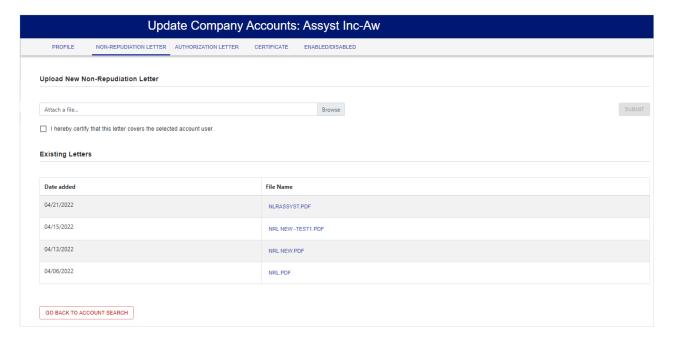
You can select the "GO BACK TO ACCOUNT SEARCH" button to select another Account to view or update.



2.5.12.2. Upload Non-Repudiation Letter for a Company Account

Once the specific Account is selected from the displayed list of the chosen Accounts for the Company, the screen for Update Company Accounts with the Profile tab is then displayed, with the current data for the selected user's profile. Select the tab for Non-Repudiation Letter.

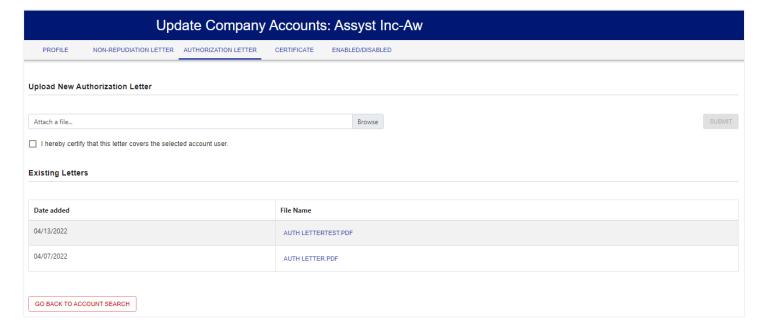
The screen for Update Company Accounts with the Non-Repudiation Letter tab is then displayed, with the current data for the selected user. Any existing letters for the Account are also displayed. Click on "Browse", to select the file for the New Non-Repudiation Letter from your computer, that needs to be uploaded. Select the checkbox for "I hereby certify that this letter covers the selected user". Then select "SUBMIT".



2.5.12.3. Upload Authorization Letter for a Company Account

Once the specific Account is selected from the displayed list of the chosen Accounts for the Company, the screen for Update Company Accounts with the Profile tab is then displayed, with the current data for the selected user's profile. Select the tab for Authorization Letter.

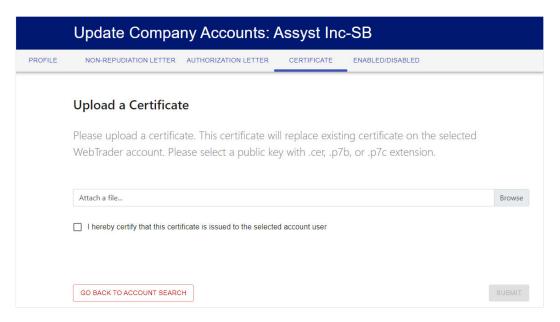
The screen for Update Company Accounts with the Authorization Letter tab is then displayed, with the current data for the selected user. Any existing letters for the Account are also displayed. Click on "Browse", to select the file for the New Non-Repudiation Letter from your computer, that needs to be uploaded. Select the checkbox for "I hereby certify that this letter covers the selected user". Then select "SUBMIT".



2.5.12.4. Upload Certificate for a Company Account

Once the specific Account is selected from the displayed list of the chosen Accounts for the Company, the screen for Update Company Accounts with the Profile tab is then displayed, with the current data for the selected user's profile. Select the tab for Certificate.

The screen for Update Company Accounts with the Certificate tab is then displayed. Click on "Browse", to select the file for the New Certificate from your computer, that needs to be uploaded. Select the checkbox for "I hereby certify that this certificate is issued to the selected user". Then select "SUBMIT".

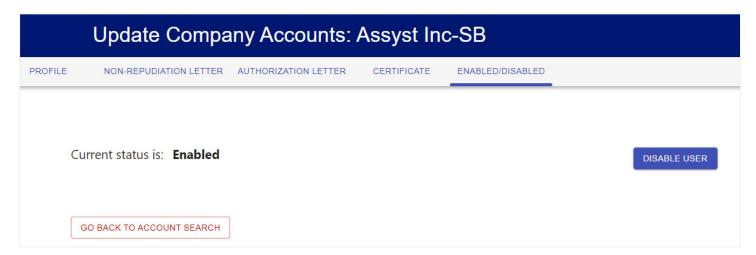


2.5.12.5. Update Status of a Company Account

Once the specific Account is selected from the displayed list of the chosen Accounts for the Company, the screen for Update Company Accounts with the Profile tab is then displayed, with the current data for the selected user's profile. Select the tab for Enabled/Disabled.

The screen for Update Company Accounts with the Enabled/Disabled tab is then displayed, with the status of the selected Account. If an Account is Enabled, you can Disable the Account by selecting "DISABLE USER". Otherwise, select "GO BACK TO ACCOUNT SEARCH", or select a menu option from the Navigation options on the left.

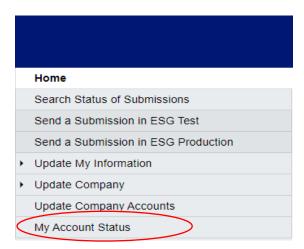
Note: The enabling of Accounts is restricted for the use of ESG FDA Admin from the ESG Help Desk.



2.5.13. View own Account Status

A Power User+ can view the status of own Account. This is useful when the Power user first requests the WT role on the Portal.

Once the Power User+ logs in, the appropriate Home page is displayed. From the menu on the left side, select "My Account Status".



The View Account Status screen is displayed, with the status of the Account for the WT role.

