FDA
Electronic Submission Gateway (ESG) NextGen
Unified Submission Portal Guide for Industry Users

Unified Submission Portal
Version 1.5
March 2026

Version History

Version Number	Implemented By	Revision Date	Approved By	Approval Date	Description of Change
1.4	Amy McKeehan	01/27/2026	Jessica Bernhardt	01/30/2026	Added Section 2.2.4: Instructions for FCTA modified workflow.
1.4	Amy McKeehan	01/27/2026	Jessica Bernhardt	01/30/2026	Updated section 7.1.2.3 with a new screenshot of the NRL grid and explained the new Employee Name column
1.5	Amy McKeehan	03/27/2026	Jessica Bernhardt	03/30/2026	Removed section 2.2.4 Modified File Catalyst Transfer Agent workflow as the system has been returned to original workflow
1.5	Amy McKeehan	03/27/2026	Jessica Bernhardt	03/30/2026	Updated screenshots in section 7.1 as edit is not available in the User Information box

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1. Introduction

1.1 Purpose of the Guide

This document outlines the functionalities, processes, and requirements for submitting regulatory information through ESG NextGen's Unified Submission Portal (USP). The guide is designed to facilitate a smooth transition to ESG NextGen, providing users with clear instructions, troubleshooting steps, and best practices.

1.2 Target Audience

This guide is intended for all industry participants using ESG NextGen to submit regulatory information to the FDA. It is applicable to users submitting on behalf of their own company as well as agents submitting on behalf of other companies. The user guide provides step-by-step instructions suitable for both new users and those transitioning from the legacy ESG system.

1.3 Overview of the Unified Submission Portal (USP)

In the context of ESG NextGen, USP is a web-based interface which serves as the primary platform for preparing, submitting, and managing electronic regulatory submissions to the FDA. The USP is also where industry users who will be submitting via Application Program Interface (API), will receive their API credentials. USP replaces the legacy ESG WebTrader interface as an intuitive, centralized portal which provides streamlined, step-by-step submission workflows.

ESG NextGen also provides submission methods via API and Applicability Statement 2 (AS2). For more information on API and AS2 functionality, refer to Section 9 Additional Training Resources.

Key features of ESG NextGen's USP include:

- Guided Submission Process: The USP provides a structured, user-friendly interface which guides users through each step of the submission process, from file upload and submission detail entry, to validation and submission.
- Submission Management: Users can easily track and manage both active and past submissions within the portal, with tools to monitor submission status, view acknowledgments (ACKs), and access submission details.
- Security and Compliance: The USP supports secure file transfers, requires multi-factor authentication (MFA), and maintains regulatory compliance and data integrity.

2. Getting Started with USP

2.1 Registering with Corporate Emails

For security and privacy reasons, ESG NextGen accepts communications via business email accounts. Public email services (e.g., Gmail, Yahoo) are not acceptable to maintain compliance and ensure data integrity. When registering for ESG NextGen, the email provided must be an individual's business email, a group or shared email cannot be used.

2.2 File Uploads via FileCatalyst Transfer Agent

ESG NextGen utilizes FileCatalyst Transfer Agent for file uploads. During the first file upload within the USP, the system will prompt users to download FileCatalyst Transfer Agent. This section outlines the necessary system requirements for using FileCatalyst Transfer Agent so users will be prepared to install FileCatalyst Transfer Agent during their first submission/file upload.

2.2.1 File Catalyst Transfer Agent System Requirements

Before downloading at the first submission, the user's system must meet the following minimum requirements to ensure compatibility with FileCatalyst Transfer Agent:

- Multi-core x64 CPU
- 8GB of RAM recommended on the machine
- Compatible operating system:
  - Windows Server 2016 or higher
  - Windows 10/11 or higher
  - macOS 10.15 or higher
  - Linux (Kernel version 4.5 or higher)
- HDD or SSD with 10GB of install space for software
- Supported web browsers:
  - Chrome
  - Edge
  - Firefox

Not Supported

- Safari web browser
- Virtual Paths
  - ESG NextGen does not support Virtual Paths in the FileCatalyst configuration on the uploader's system. Configuring a path at the FileCatalyst Configuration Virtual Paths will result in submissions being stuck in 'Upload Received' status.

2.2.2. FileCatalyst TransferAgent Installation Process

Users do not need to visit the FileCatalyst website to download the software. FileCatalyst Transfer Agent will automatically prompt for installation during the user's first submission. This integration ensures a seamless experience for users.

- During the first file upload:

- The system will detect if FileCatalyst Transfer Agent is not installed.
- Users will receive an automatic prompt to install FileCatalyst Transfer Agent within their browser.
- Follow the on-screen instructions to complete the installation.

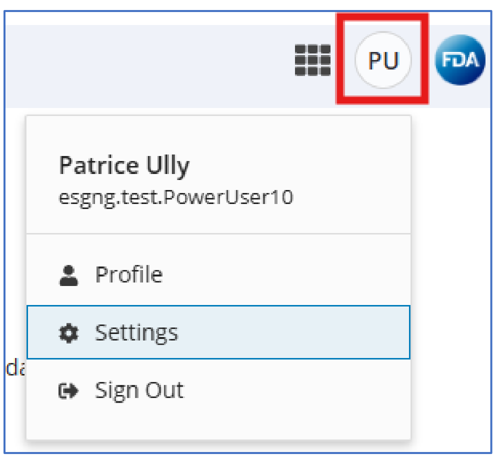
2.2.3 Important FileCatalyst Transfer Agent Note for Troubleshooting

Although users will not need to download FileCatalyst Transfer Agent manually, troubleshooting information is available if the installation or operation encounters issues. Verify network configurations and ensure the system has the necessary permissions to install and run the FileCatalyst Transfer Agent software. If your organization has an Information Technology resource, they should be able to verify configuration permissions. Please contact ESGNGSupport@fda.hhs.gov if further assistance is required.

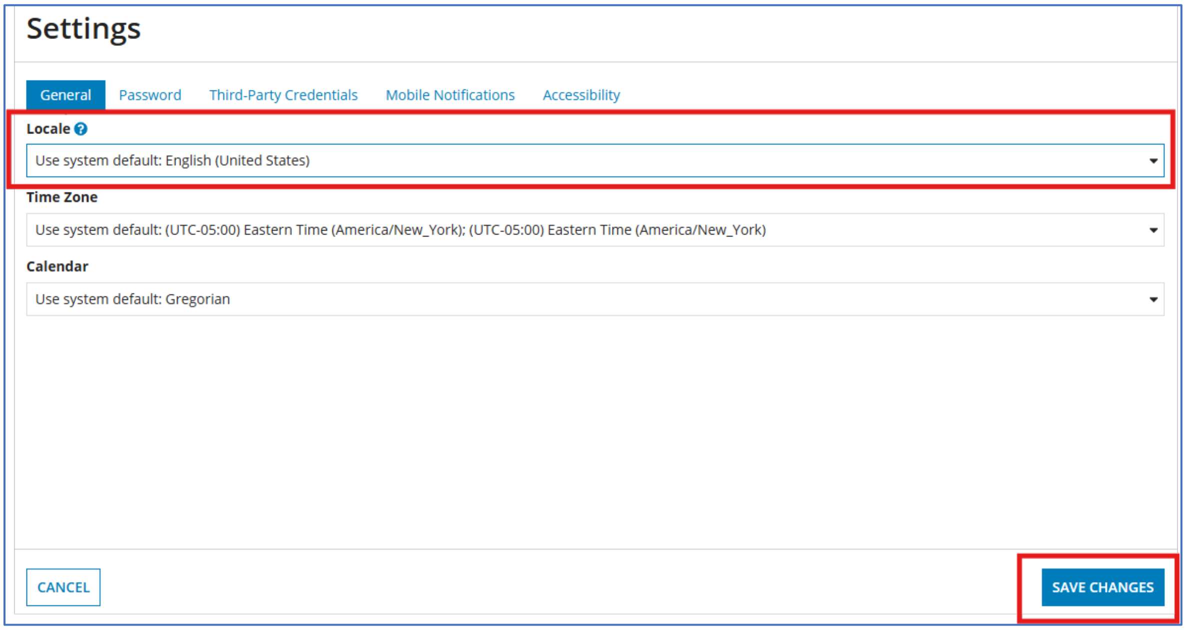
2.3 French Language Translation

In accordance with our Health Canada partnership, ESG NextGen supports French language translation of the USP. Below are the steps for setting your language to French.

1. Log into ESG NextGen USP.
2. Click your initials in the upper right-hand corner of the screen and select settings.



3. Adjust your language with the Locale dropdown. Select ‘Français (Canada)’ and click ‘Save Changes’.



3. User Registration and Access

3.1 User Roles and Permissions

ESG NextGen defines two primary user roles, each with distinct permission:

- **Power User:**
  Power Users have full access to all system functionalities, including user registration, company and user management, and submission processes. Power Users are allowed to:
  - Manage company information such as Non-Repudiation Letters and Authorization Letters. (For more information on Non-Repudiation Letters and Authorization Letters, refer to Letters of Non-Repudiation Agreement | FDA and Authorization Letter | FDA.
  - Generate API credentials. For more information on API Management, refer to ESG NextGen API Guide for Industry Users and the API Management training video.
  - Manage users (roles and permissions) within their organization.
  - Upload submissions.
  - View all submissions and submission statuses within their organization.
- **Submitter:**
  Submitters are authorized to submit regulatory files for their company but cannot manage users or modify company settings. Submitters focus on preparing and sending both test and production submissions through the USP. Submitters are allowed to:

- Upload submissions.
- View their own submissions and submission statuses.
- View/edit their user information.

3.2 Agent, Contract Research Organization (CRO), or Consultant Registration

Agents, CROs, or Consultants that submit on behalf of multiple clients will register under their own company. The Authorization Letters uploaded by the Agent, CRO, or Consultant, is what will link the Agent, CRO, or Consultant company to the companies they are submitting on behalf of. Please follow the steps outlined below in Registering for a USP Account when creating your account.

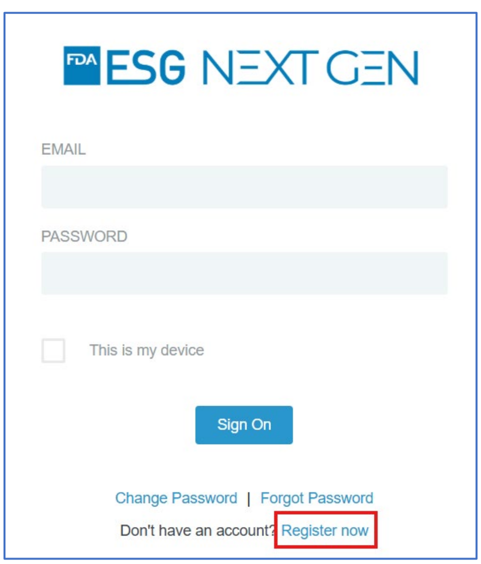
3.3 Registering for a USP Account

To utilize the functionality within ESG NextGen USP, users will need to register for a USP account. If you have already created an ESG NextGen USP account, please use the credentials created during account registration to log in to your account.

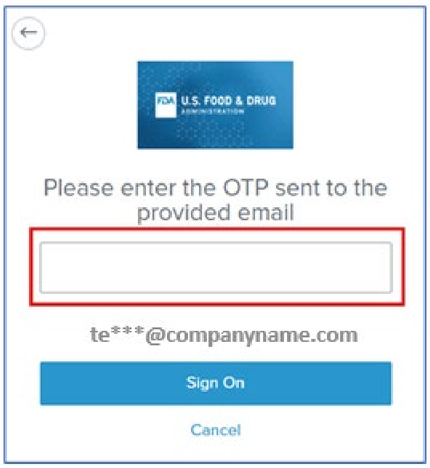
Step 1: Create Log In Credentials and set-up Multi-Factor Authentication

1. Open your browser (Chrome, Firefox, or Edge) and navigate to the web page [Electronic Submissions Gateway | FDA]
2. Click on 'Industry USP Log In'.

3. Review the Security Warning and click 'Accept'.
4. On the ESG NextGen log in page, click on 'Register now'.



- Enter all required information on the 'Create Your Account' page and then click 'Create Account'.
    - An email will be sent to the email address entered during this registration process stating your account has been created.
- Enter the credentials created while registering your account in the ESG NextGen log in screen and click 'Sign On'.
- Go to the email inbox for the email entered during registration to obtain the One Time Passcode (OTP).
- Enter the OTP in the box provided and click 'Sign On'.



- You are now Authenticated and will be directed to ESG NextGen USP.

Step 2: Complete ESG NextGen Registration

The ESG NextGen USP registration wizard will walk you through the steps to complete your ESG NextGen USP registration.

Legacy ESG Users

For users with an active legacy ESG account, your user information has been migrated to ESG NextGen, and you remain covered under your previously submitted Non-Repudiation Letter and Authorization Letter (if needed). Once logged in to ESG NextGen USP for the first time, please review the information presented and click 'Continue' to activate your ESG NextGen USP account.

New Users

For users new to submitting to the FDA via legacy ESG or ESG NextGen, you will need to review the guidelines for a Non-Repudiation Letter found here: [Letters of Non-Repudiation Agreement]

| FDA. For Agents, CROs, and Consultants submitting on behalf of another company, please also reference the guidelines for Authorization Letters: Authorization Letter | FDA

Within the ESG NextGen USP registration wizard, you will have the option to upload a signed Non-Repudiation Letter, or you can create a Non-Repudiation Letter digitally within the wizard and sign electronically.

For Agents, CRO's, and Consultants registering their company with ESG NextGen, be sure to check the box for 'This company is an agency/consulting firm submitting on behalf of other companies.' This will indicate to the system that users for your company will be uploading on behalf of other companies. During the registration process, at least one Authorization Letter will need to be uploaded.

There are multiple ways the ESG NextGen USP registration wizard will walk you through the registration process. Please reference the following training videos for more information on the ESG NextGen USP registration process:

New Company/New User Registration

- New Company Agent Upload User Registration: Covers entering your company's information and uploading a Non-Repudiation Letter.
- New Company Non-Agent Duplicate Upload User Registration: Covers entering your company's information and a duplicate company is detected, and a Non-Repudiation Letter is uploaded.
- New Company Non-Agent Duplicates Digital User Registration: Covers entering your company's information and duplicate companies are detected and a digital Non-Repudiation Letter is created.

Existing Company/New User Registration

- Existing Shell Digital User Registration: Company selected is just the company name created by an Agent to submit on behalf of the selected company. Registering user is defaulted to a Power User and a digital Non-Repudiation Letter is created.
- Existing Non-Shell Upload User Registration: Registering user found their company and uploaded a Non-Repudiation Letter.
- Existing Non-Shell Letter Found User Registration: Registering user found their company and is covered under a company-wide Non-Repudiation Letter.

For a new user registering under an existing company within ESG NextGen, once your ESG NextGen USP registration is complete, a Power User from your company will review and accept or decline your registration. An email notification will be sent to you notifying you of the status of your ESG NextGen USP account.

For a new company entered into ESG NextGen with the new user registration, an ESG NextGen Admin will review your registration, and an email notification will be sent to you notifying you of the status of your ESG NextGen USP account. The first user registered in a company will default to a Power User role.

4. USP System Navigation

4.1 Left Navigation Menu

The ESG NextGen USP left navigation menu allows users to navigate within the USP. Details pertaining to each option in the USP left navigation menu will be provided in their own sections of this guide. All users will have access to:

- New Production Submission
- Dashboard
- Submission History
- Test Submission
- User Management

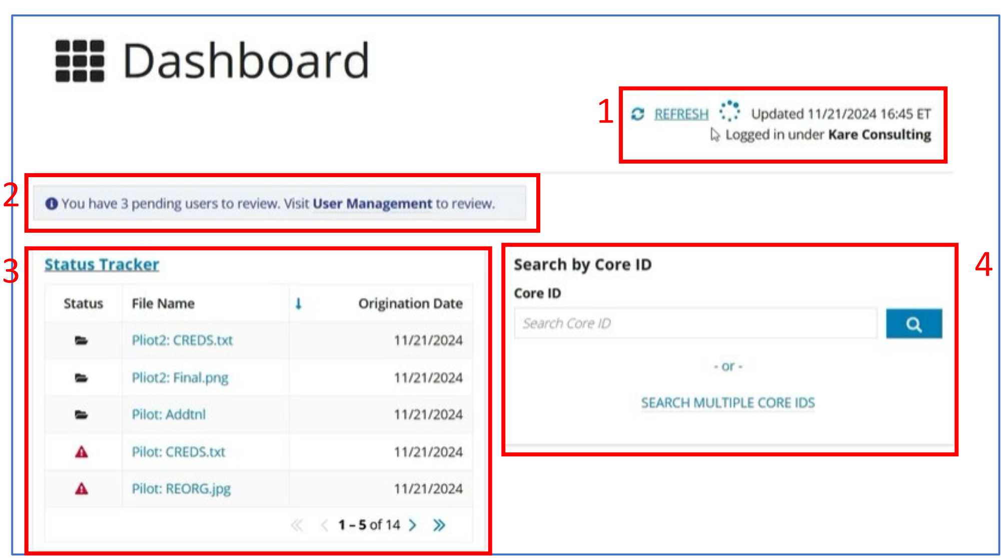
Power Users will also have access to:

- API Management

For further information pertaining to API Management, please reference the ESG NextGen API Guide for Industry Users, which can be found at User Guides.

4.2 Dashboard

The ESG NextGen USP Dashboard is where users will land once logged in. The USP Dashboard provides important information for the user.



1. The upper right-hand corner of the USP Dashboard provides the user with the date/time of the last page refresh. Users are also able to manually refresh the page by clicking 'Refresh'. Lastly, the company the user is logged in under will display.
2. Power Users will have notices for when there are user accounts which need to be reviewed. By clicking the 'User Management' link in the notice, the user will be taken to User Management.
3. The Status Tracker provides an "at a glance" view of up to 50 submissions to ESG NextGen within the last month. The Status Tracker provides the Status, the File Name, and the Origination Date of the submission. Below are the definitions of each of the Status icons.

Upload Initiated	**Upload Failed**	**Cancelled**
Upload in Progress	**Submitted to Center**	**Failed: Exceeds Center Submission Size Guideline**
Upload Received	**Center's Response Sent**	

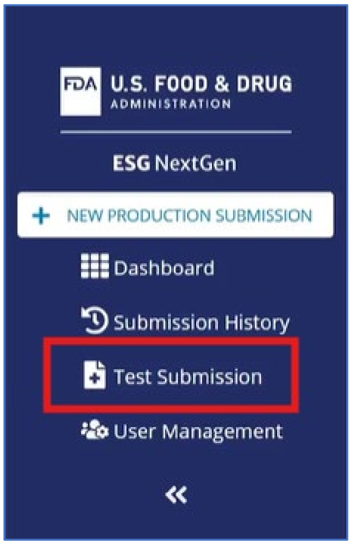
4. Search by Core ID allows the user to quickly find a specific submission. By clicking on 'Search Multiple Core IDs', the user is navigated to the Submission History screen where a box will open by the Core ID search parameter, allowing the user to define their delimiter and insert their list of Core IDs to search on. For more information on Submission History functionality, refer to Section 6.2 Submission History.

5. Submissions via USP

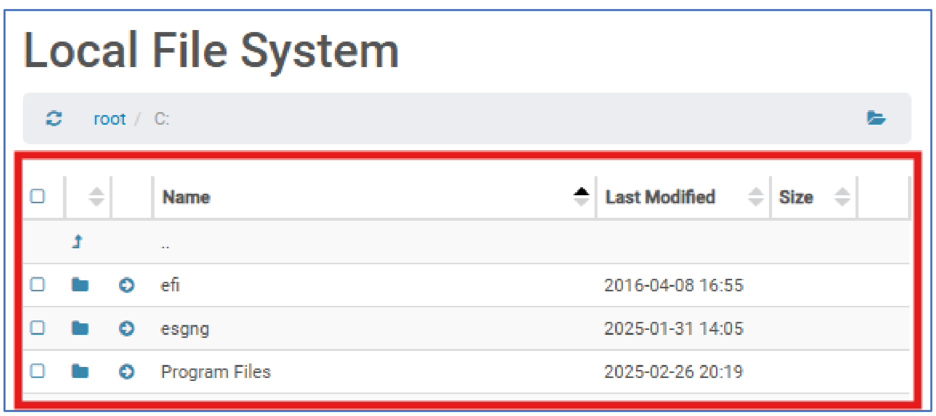
ESG NextGen USP users are able to perform Test and Production submission uploads within the same user interface. ESG NextGen will transmit submissions to their appropriate location based on whether a Test or Production submission was selected. This capability eliminates the need to have separate test and production accounts.

5.1 Test Submission for Non-Agents, CROs, or Consultants

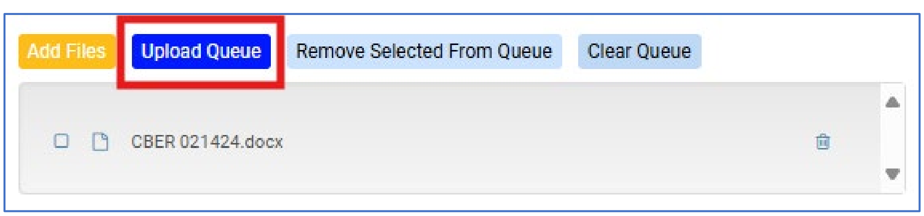
1. Log into ESG NextGen USP.
2. In the left navigation menu, click on 'Test Submission'.



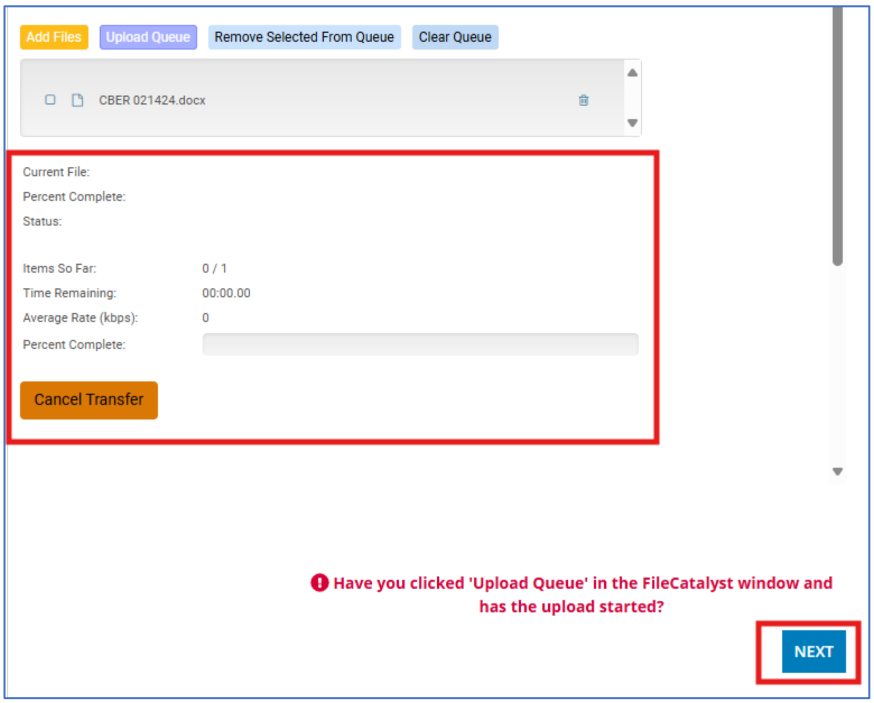
3. The File Catalyst TransferAgent window will appear.
    - If this is your first submission via ESG NextGen USP, you will be prompted to download FileCatalyst Transfer Agent. For more information on downloading FileCatalyst Transfer Agent, refer to Section 2 Getting Started with USP.
4. Through the FileCatalyst Transfer Agent window, navigate to your file within your Local File System.



5. Select the file(s) to be uploaded and click Upload Queue.

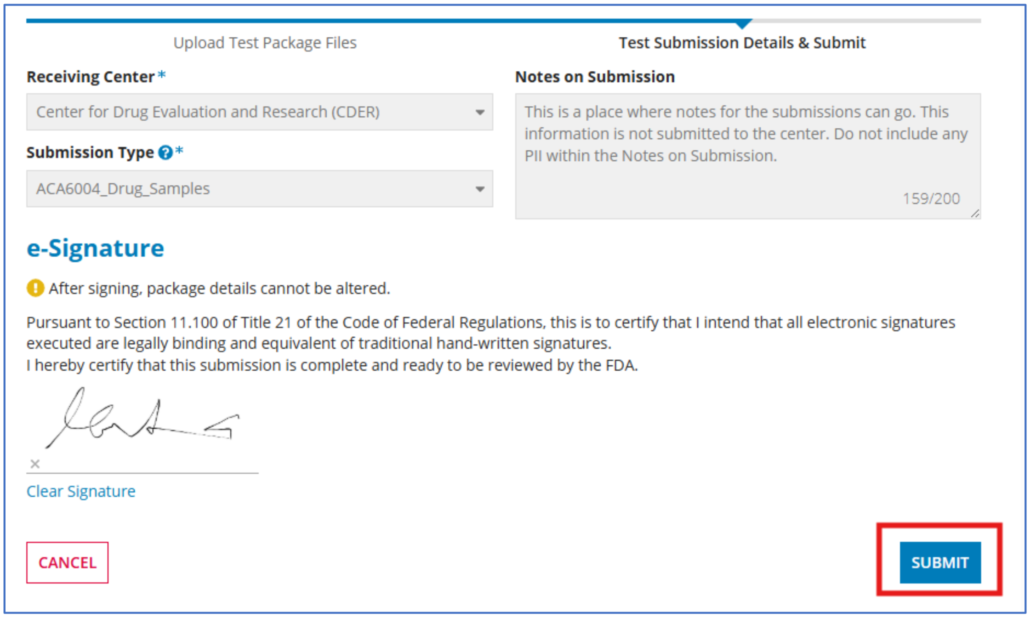


6. Once the upload has started, click ‘Next’.
    - Note: The upload will continue in the background and complete without remaining on the page. For larger file uploads, do not wait on this page for the upload to complete. The USP will log users out after 20 minutes of inactivity. If a new submission has not proceeded to the next page and the ‘Submit’ button has not been clicked, the system will cancel the submission.



7. On the Test Submission Details & Submit page, complete the details of the submission.
    - Select the Receiving Center.
    - Select the Submission Type.
    - Notes of Submission is an optional field and can be used to provide additional details around the submissions. This information is not passed on to the Centers. It is a reference field for the submitter.
    - Electronically sign the submission by drawing your signature in the field with your mouse, finger, or stylus pen. This field is referred to as e-Signature.
        - If corrections to any field above e-Signature needs to be made after e-signing, click ‘Clear Signature’ to enable editing of the fields. Once corrections are made, the submission will need to be e-signed again.

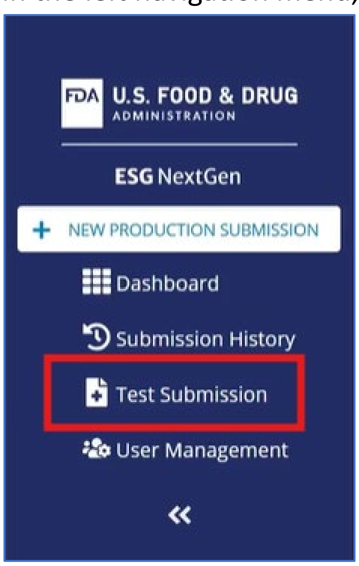
8. Once all fields are completed and reviewed, click 'Submit' to complete the process of uploading a Test Submission.



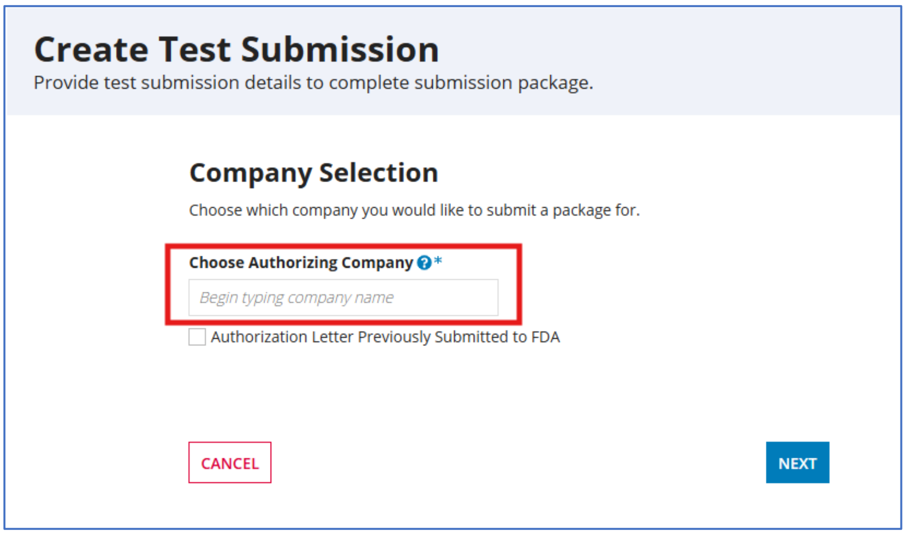
5.2 Test Submissions for Agents, CROs, or Consultants Migrated from Legacy ESG

1. Log into ESG NextGen USP.

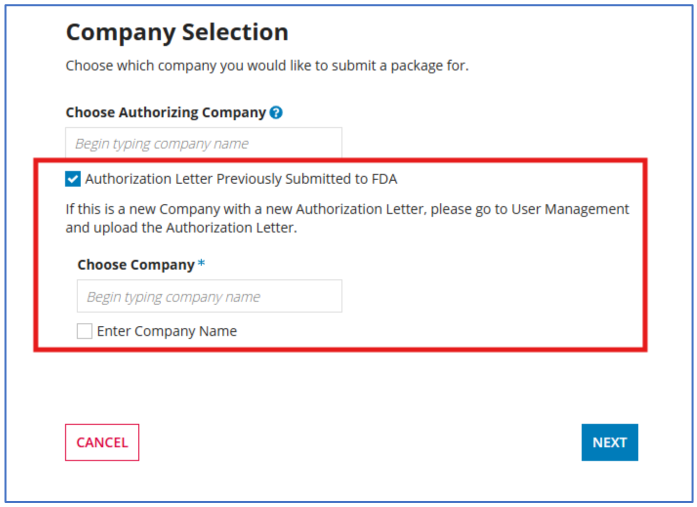
2. In the left navigation menu, click on 'Test Submission'.



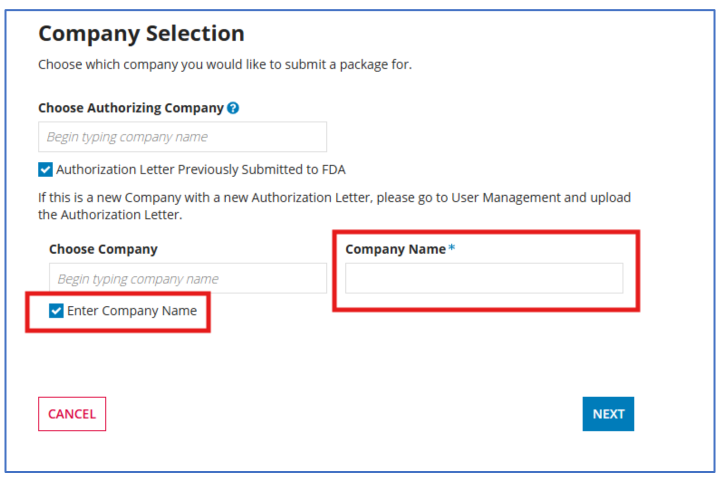
3. Begin typing the company name in the 'Choose the Authorizing Company' box to auto search and select the Authorizing Company the submission is being uploaded on their behalf.
   - This dropdown is populated by the Authorization Letters which have been uploaded into ESG NextGen. The uploaded Authorization Letters can be viewed in User Management by Power Users. For more information on User Management, refer to Section 7 User Management.



   - If the company the submission is being uploaded for is not listed AND an Authorization Letter was previously submitted to the FDA, check the box for 'Authorization Letter Previously Submitted to FDA'. This option applies to companies migrated from legacy ESG to ESG NextGen.
     - Once checked, a 'Choose Company' dropdown is available and users can search for the company they are submitting on behalf of.



- If the user cannot find the company they are submitting on behalf of, check the box for 'Enter Company Name' and a 'Company Name' box will appear where the company name can be entered.

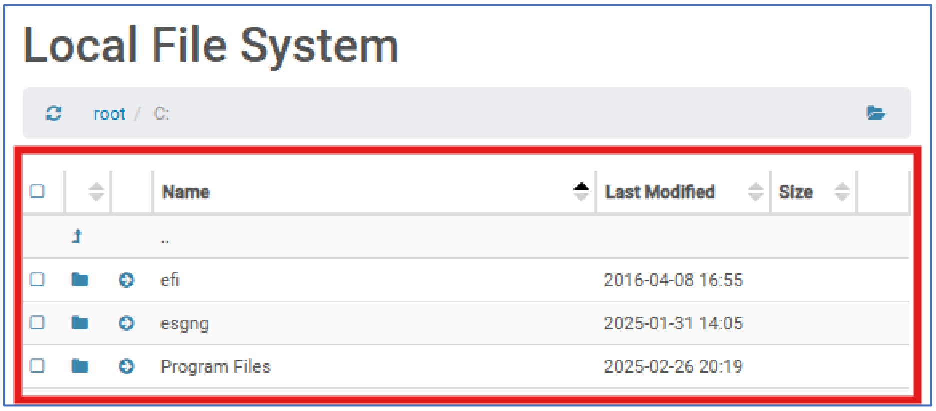


  - If an Authorization Letter has never been submitted to the FDA for the company the submission is for, proceed to User Management to upload the Authorization Letter.
  - If the Company Name is manually typed in, ESG NextGen will save this company in User Management / Authorization Letter and indicate Letter is on File. This allows for the manually typed in company to appear in the 'Choose Authorizing Company' dropdown box when doing another submission for the company.
    - DO NOT manually enter the same company name every time an upload is done for the company.

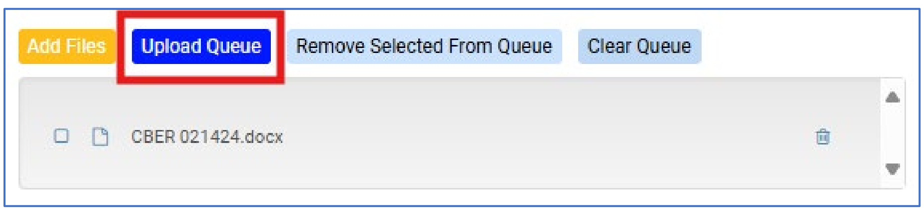
4. Once the company the user is submitting on behalf of is selected or entered, click 'Next'.
5. The File Catalyst TransferAgent window will appear.

- If this is your first submission via ESG NextGen USP, you will be prompted to download FileCatalyst Transfer Agent. For more information on downloading FileCatalyst Transfer Agent, refer to Section 2 Getting Started with USP.

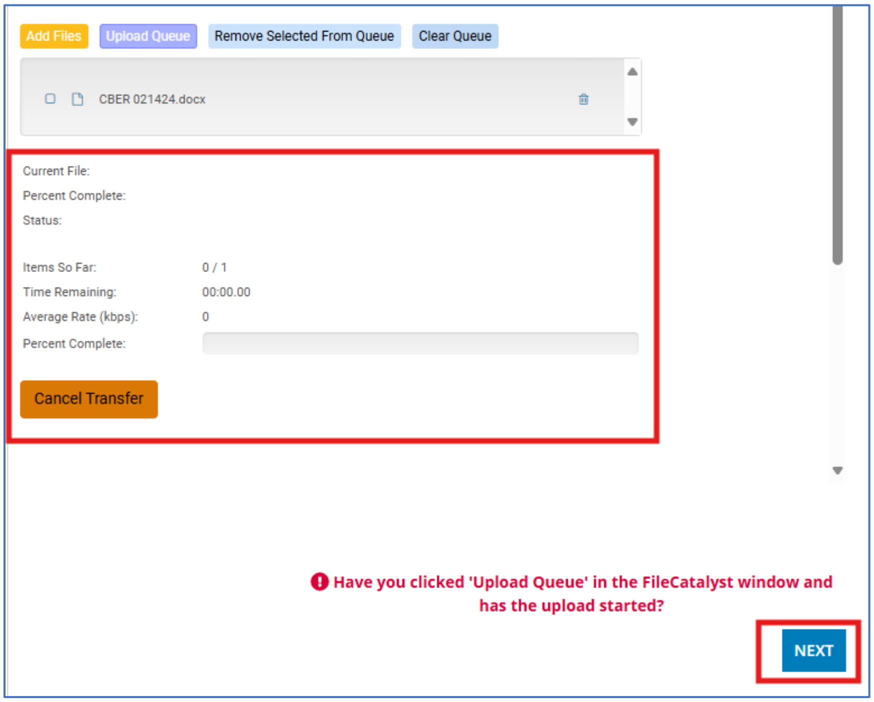
6. Through the FileCatalyst Transfer Agent window, navigate to your file within your Local File System.



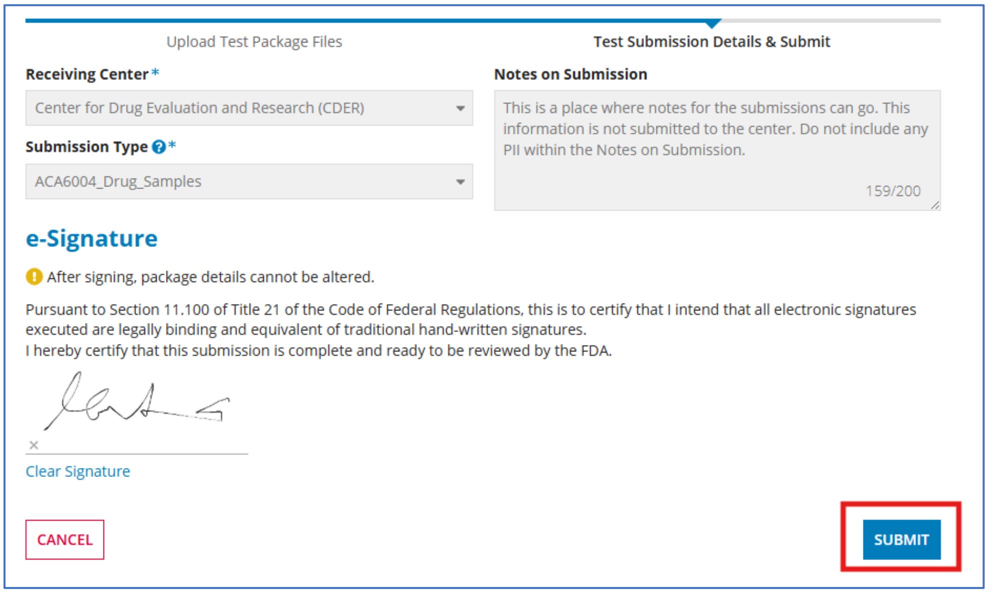
7. Select the file(s) to be uploaded and click Upload Queue.



8. Once the upload has started, click ‘Next’.
   - Note: The upload will continue in the background and complete without remaining on the page. For larger file uploads, do not wait on this page for the upload to complete. The USP will log users out after 20 minutes of inactivity. If a new submission has not proceeded to the next page and the ‘Submit’ button has not been clicked, the system will cancel the submission.

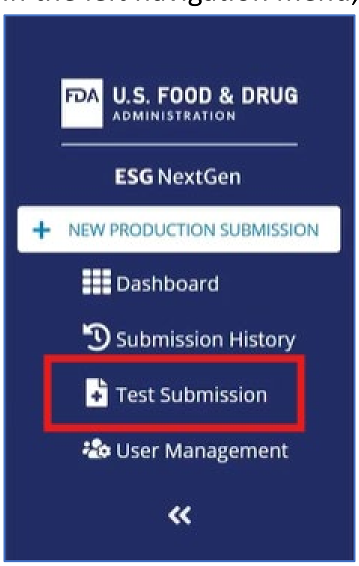


9. On the Test Submission Details & Submit page, complete the details of the submission.
   - Select the Receiving Center.
   - Select the Submission Type.
   - Notes of Submission is an optional field and can be used to provide additional details around the submissions. This information is not passed on to the Centers. It is a reference field for the submitter.
   - Electronically sign the submission by drawing your signature in the field with your mouse, finger, or stylus pen. This field is referred to as e-Signature.
     - If corrections to any field above e-Signature need to be made after e-signing, click ‘Clear Signature’ to enable editing of the fields. Once corrections are made, the submission will need to be e-signed again.
10. Once all fields are completed and reviewed, click ‘Submit’ to complete the process of uploading a Test Submission.



5.3 Test Submissions for Agents, CROs, or Consultants with a New Company in ESG NextGen

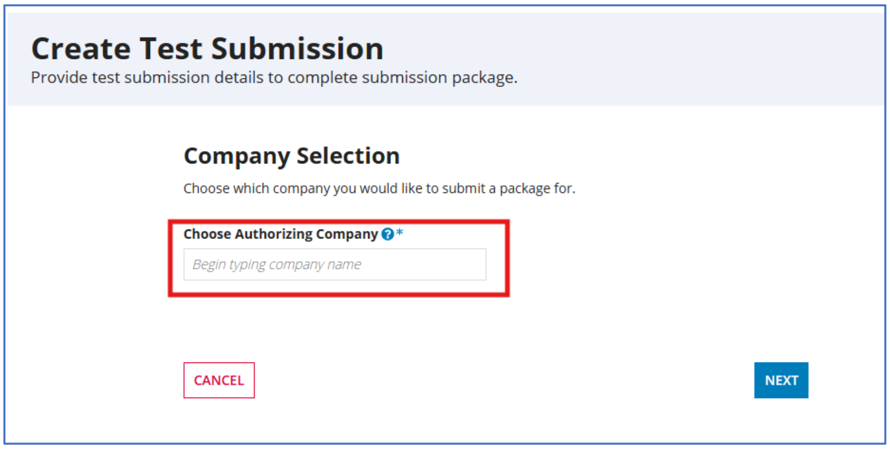
1. Log into ESG NextGen USP.
2. In the left navigation menu, click on 'Test Submission'.



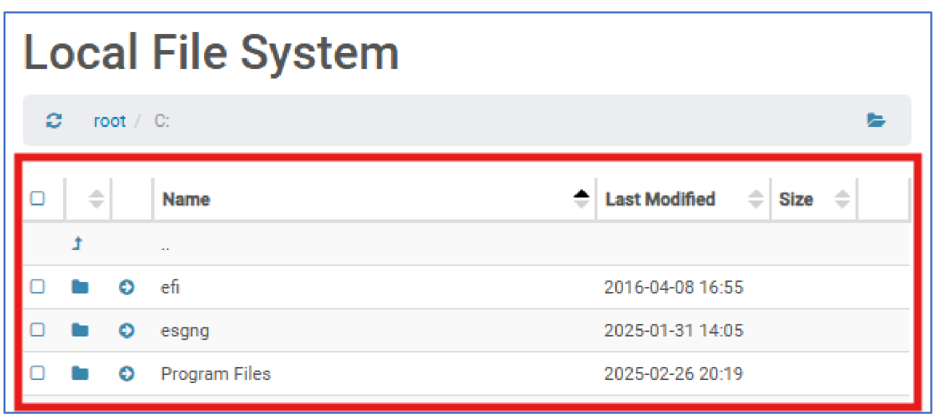
3. Begin typing the company name in the 'Choose the Authorizing Company' box to auto search and select the Authorizing Company the submission is being uploaded on their behalf.
   - This dropdown is populated by the Authorization Letters which have been uploaded into ESG NextGen. The uploaded Authorization Letters can be viewed

in User Management by Power Users. For more information on User Management, refer to Section 7 User Management.

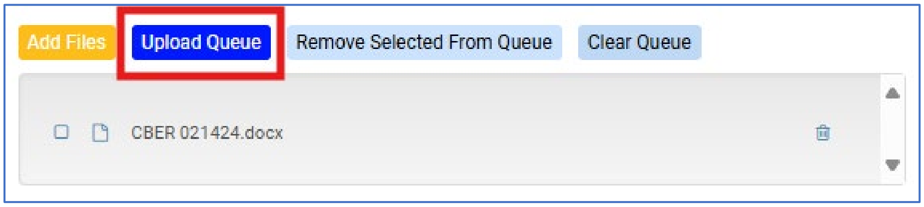
- If an Authorization Letter has never been submitted to the FDA for the company the submission is for, proceed to User Management to upload the Authorization Letter.



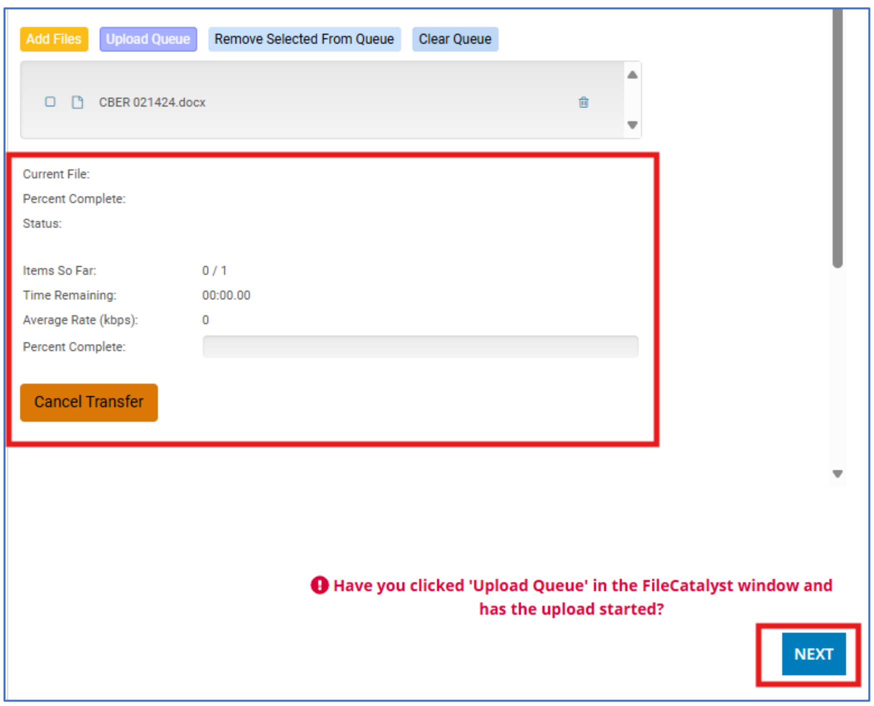
4. Once the company the user is submitting on behalf of is selected, click 'Next'.
5. The File Catalyst TransferAgent window will appear.
   - If this is your first submission via ESG NextGen USP, you will be prompted to download FileCatalyst Transfer Agent. For more information on downloading FileCatalyst Transfer Agent, refer to Section 2 Getting Started with USP.
6. Through the FileCatalyst Transfer Agent window, navigate to your file within your Local File System.



7. Select the file(s) to be uploaded and click Upload Queue.



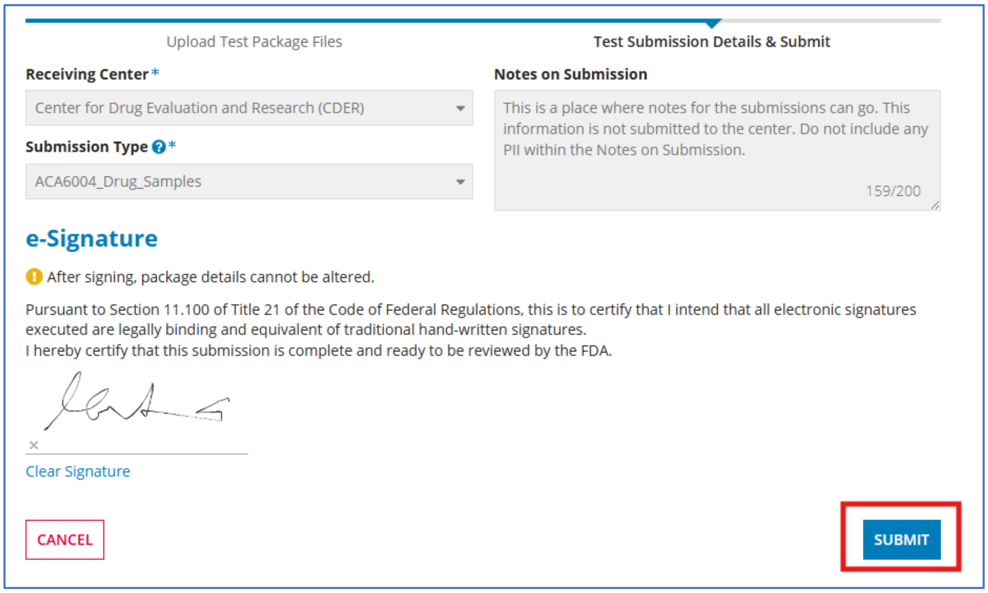
8. Once the upload has started, click 'Next'.
    - Note: The upload will continue in the background and complete without remaining on the page. For larger file uploads, do not wait on this page for the upload to complete. The USP will log users out after 20 minutes of inactivity. If a new submission has not proceeded to the next page and the 'Submit' button has not beenclicked, the system will cancel the submission.



9. On the Test Submission Details & Submit page, complete the details of the submission.
    - Select the Receiving Center.
    - Select the Submission Type.
    - Notes of Submission is an optional field and can be used to provide additional details around the submissions. This information is not passed on to the Centers. It is a reference field for the submitter.

- Electronically sign the submission by drawing your signature in the field with your mouse, finger, or stylus pen. This field is referred to as e-Signature.
    - If corrections to any field above e-Signature need to be made after e-signing, click 'Clear Signature' to enable editing of the fields. Once corrections are made, the submission will need to be e-signed again.

10. Once all fields are completed and reviewed, click 'Submit' to complete the process of uploading a Test Submission.



5.4 When to do a Test Submission

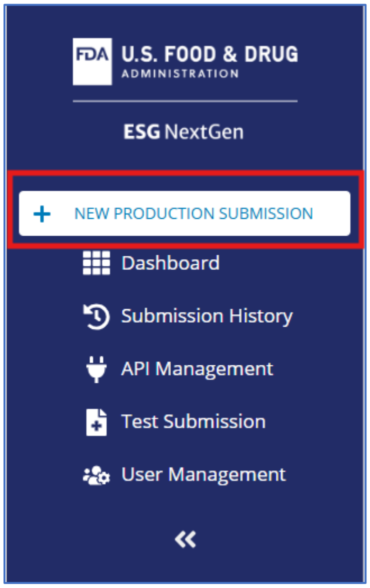
A test submission can be submitted at any time the user wants to validate files.

A user who has never submitted to the FDA through legacy ESG is referred to as a "net new" user. If a user is a net new user to ESG NextGen, the user may be required to upload a test submission prior to gaining access to all production Center/Submission Types. This test submission is only required for the Center/Submission Types which require a test submission prior to allowing a net new ESG NextGen user to submit a production submission. The Center/Submission Types which require a test submission for net new ESG NextGen users can be found here.

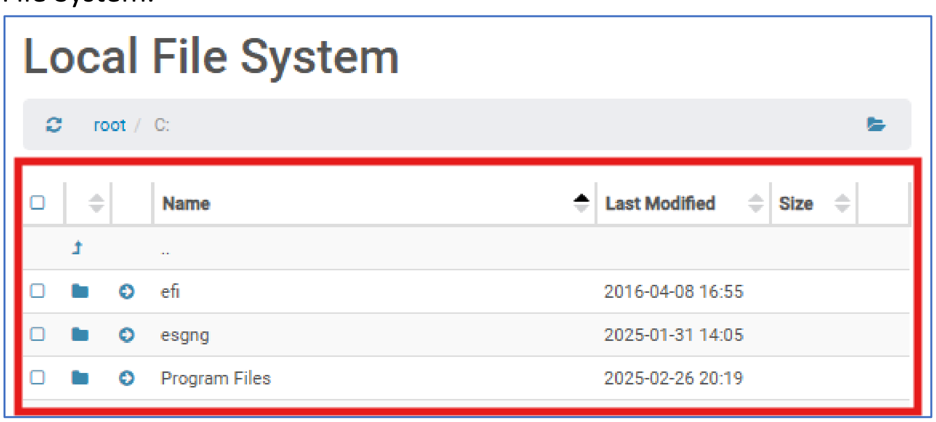
Any user can determine if they need to perform a test submission in order to have access to all production submissions, by navigating to User Management / My Information / User Information. For more information on User Management, refer to Section 7 User Management.

5.5 Production Submissions for Non-Agents, CROs, or Consultants

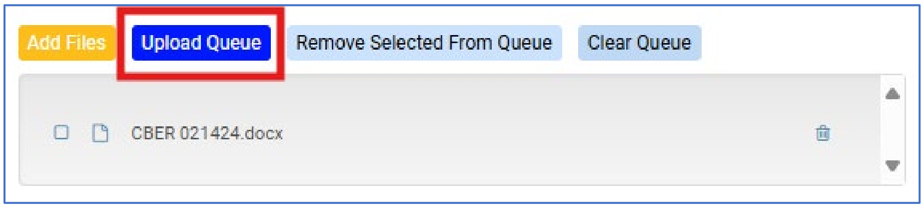
1. Log into ESG NextGen USP.
2. In the left navigation menu, click on 'New Production Submission'.



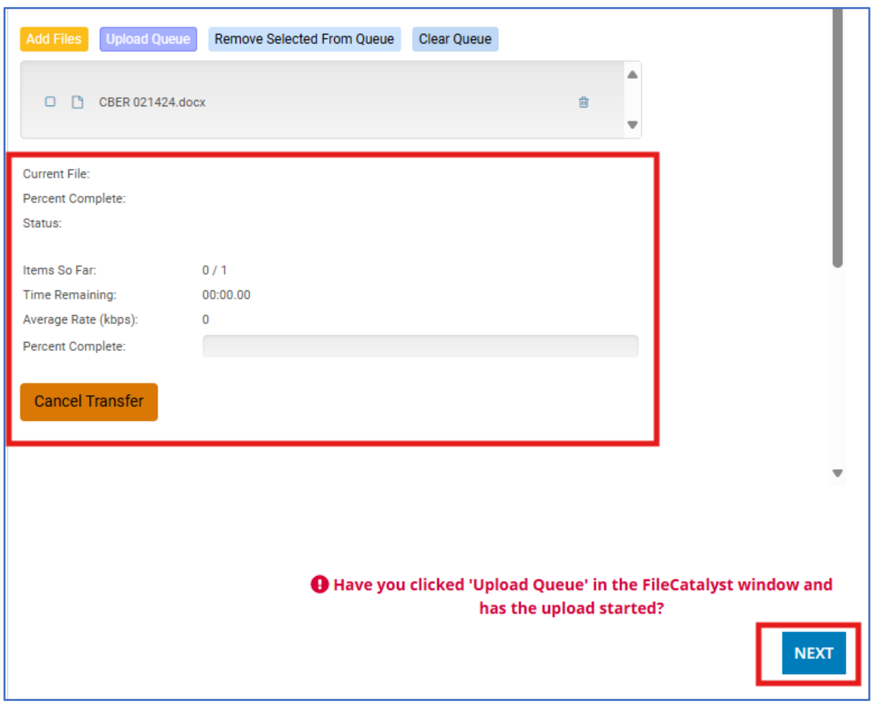
3. The File Catalyst TransferAgent window will appear.
    - If this is your first submission via ESG NextGen USP, you will be prompted to download FileCatalyst Transfer Agent. For more information on downloading FileCatalyst Transfer Agent, refer to Section 2 Getting Started with USP.
4. Through the FileCatalyst Transfer Agent window, navigate to your file within your Local File System.



5. Select the file(s) to be uploaded and click Upload Queue.



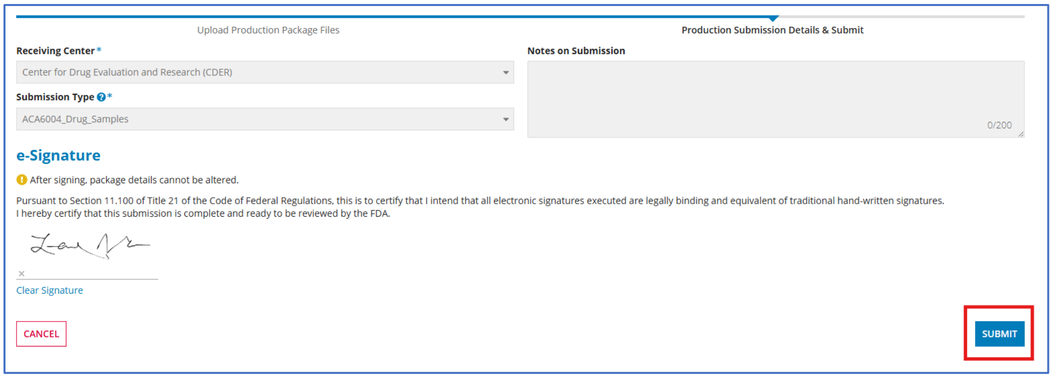
6. Once the upload has started, click 'Next'.
   - Note: The upload will continue in the background and complete without remaining on the page. For larger file uploads, do not wait on this page for the upload to complete. The USP will log users out after 20 minutes of inactivity. If a new submission has not proceeded to the next page and the 'Submit' button has not been clicked, the system will cancel the submission.



7. On the Production Submission Details & Submit page, complete the details of the submission.
   - Select the Receiving Center.
   - Select the Submission Type.
   - Notes of Submission is an optional field and can be used to provide additional details around the submissions. This information is not passed on to the Centers. It is a reference field for the submitter.
   - Electronically sign the submission by drawing your signature in the field with your mouse, finger, or stylus pen. This field is referred to as e-Signature.

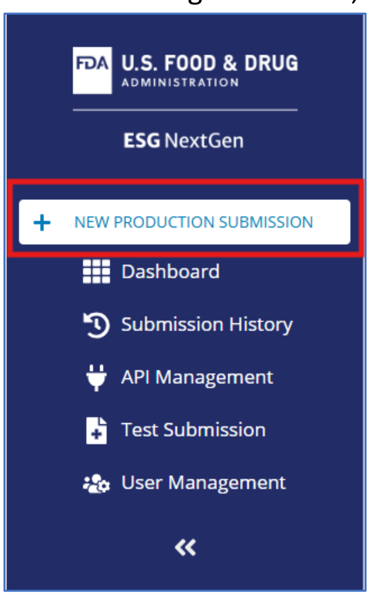
- If corrections to any field above e-Signature need to be made after e-signing, click 'Clear Signature' to enable editing of the fields. Once corrections are made, the submission will need to be e-signed again.

8. Once all fields are completed and reviewed, click 'Submit' to complete the process of uploading a Production Submission.



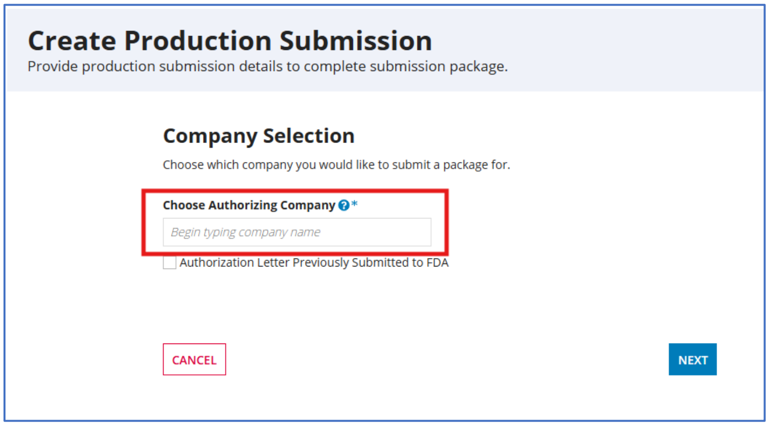
5.6 Production Submissions for Agents, CROs, or Consultants Migrated from Legacy ESG

1. Log into ESG NextGen USP.
2. In the left navigation menu, click on 'New Production Submission'.

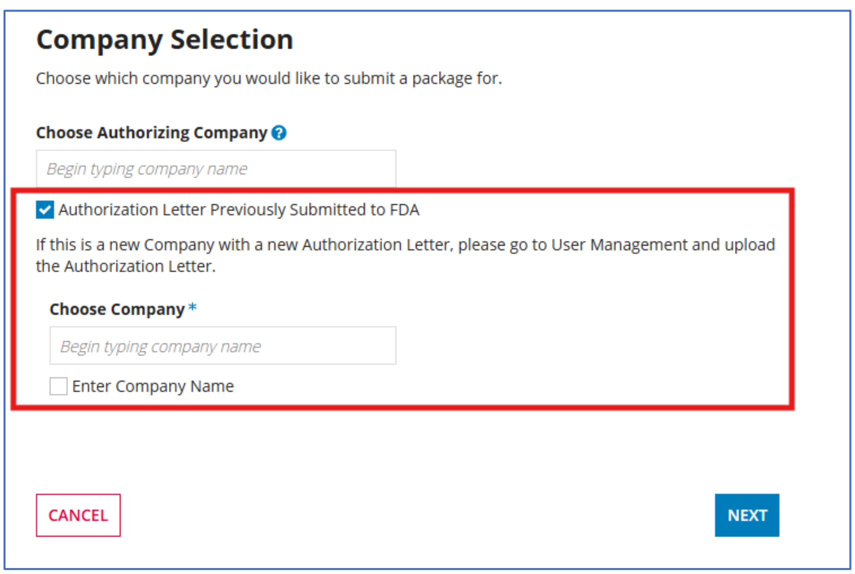


3. Begin typing the company name in the 'Choose the Authorizing Company' box to auto search and select the Authorizing Company the submission is being uploaded on their behalf.
   - This dropdown is populated by the Authorization Letters which have been uploaded into ESG NextGen. The uploaded Authorization Letters can be viewed

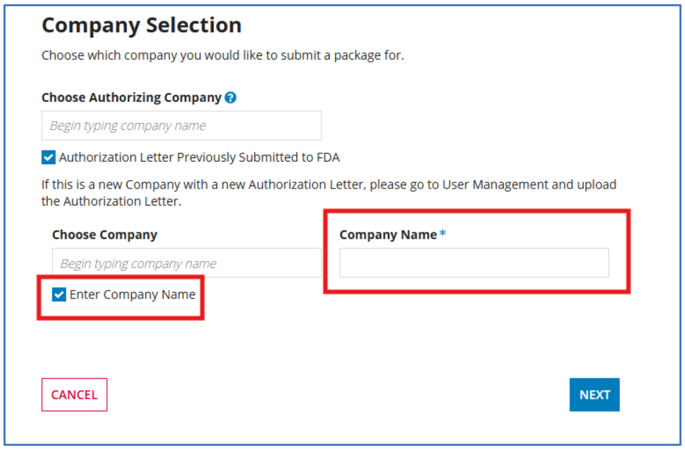
in User Management by Power Users. For more information on User Management, refer to Section 7 User Management.



- ○ If the company the submission is being uploaded for is not listed AND an Authorization Letter was previously submitted to the FDA, check the box for 'Authorization Letter Previously Submitted to FDA'. This option applies to companies migrated from legacy ESG to ESG NextGen.
  - Once checked, a 'Choose Company' dropdown is available, and users can search for the company they are submitting on behalf of.

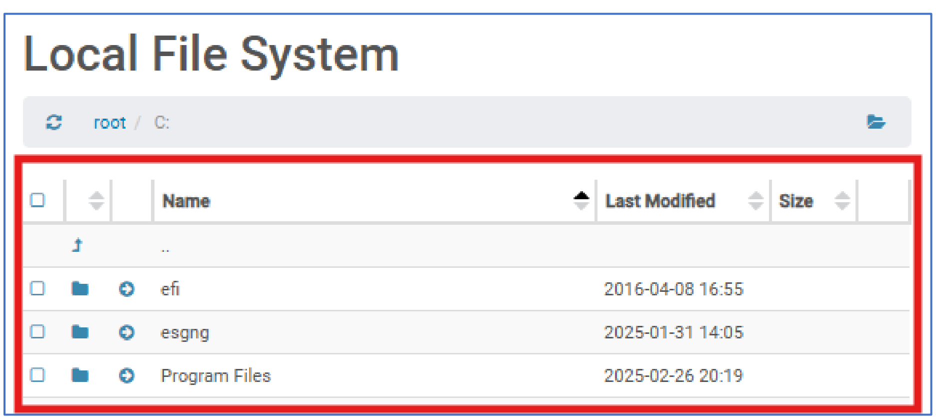


  - If the user cannot find the company they are submitting on behalf of, check the box for 'Enter Company Name' and a 'Company Name' box will appear where the company name can be entered.

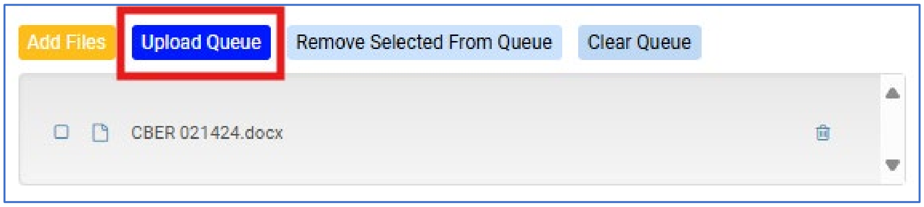


- If an Authorization Letter has never been submitted to the FDA for the company the submission is for, proceed to User Management to upload the Authorization Letter. For more information on User Management, refer to Section 7 User Management.
- If the Company Name is manually typed in, ESG NextGen will save this company in User Management / Authorization Letter and indicate Letter is on File. This allows for the manually typed in company to appear in the 'Choose Authorizing Company' dropdown box when doing another submission for the company.
    - DO NOT manually enter the same company name every time an upload is done for the company.

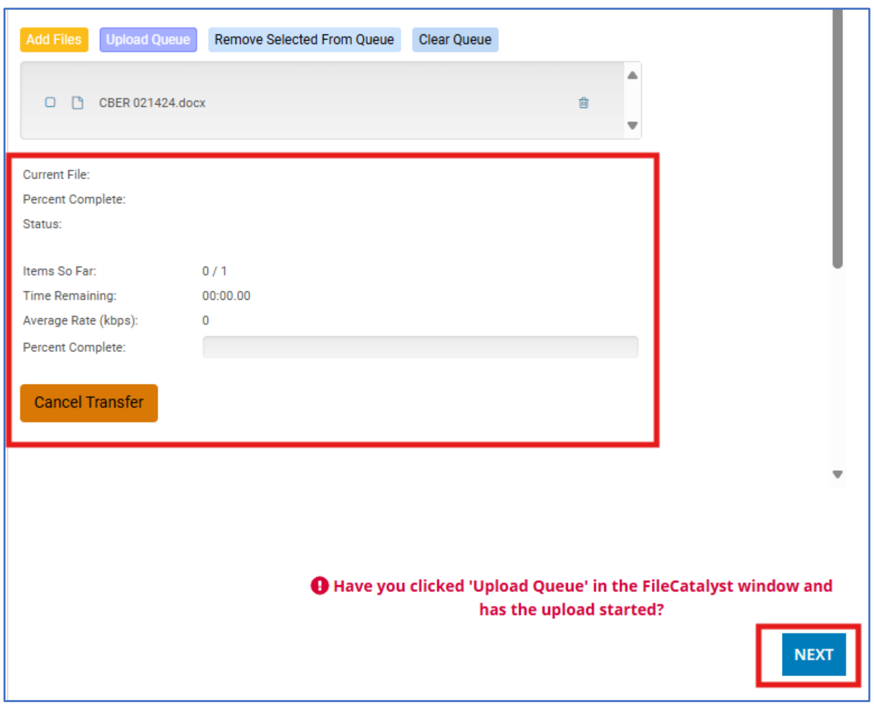
4. Once the company the user is submitting on behalf of is selected or entered, click 'Next'.
5. The File Catalyst TransferAgent window will appear.
    - If this is your first submission via ESG NextGen USP, you will be prompted to download FileCatalyst Transfer Agent. For more information on downloading FileCatalyst Transfer Agent, refer to Section 2 Getting Started with USP.
6. Through the FileCatalyst Transfer Agent window, navigate to your file within your Local File System.



7. Select the file(s) to be uploaded and click Upload Queue.



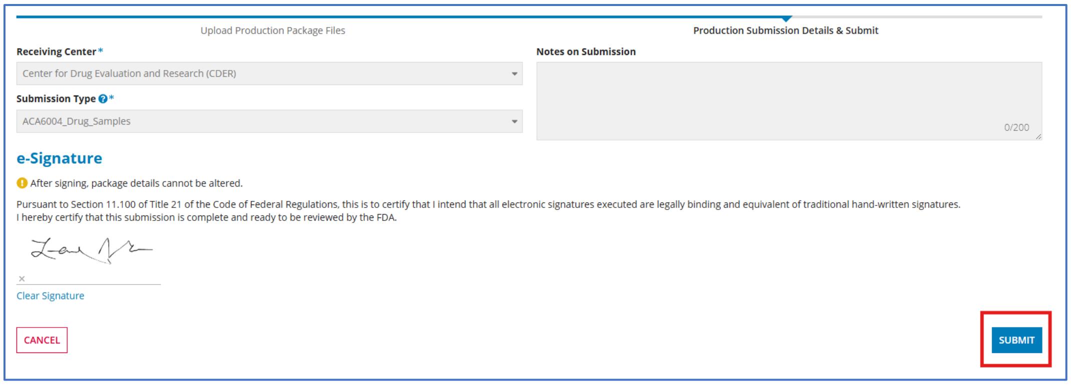
8. Once the upload has started, click 'Next'.
    - Note: The upload will continue in the background and complete without remaining on the page. For larger file uploads, do not wait on this page for the upload to complete. The USP will log users out after 20 minutes of inactivity. If a new submission has not proceeded to the next page and the 'Submit' button has not been clicked, the system will cancel the submission.



9. On the Production Submission Details & Submit page, complete the details of the submission.
    - Select the Receiving Center.
    - Select the Submission Type.
    - Notes of Submission is an optional field and can be used to provide additional details around the submissions. This information is not passed on to the Centers. It is a reference field for the submitter.
    - Electronically sign the submission by drawing your signature in the field with your mouse, finger, or stylus pen. This field is referred to as e-Signature.

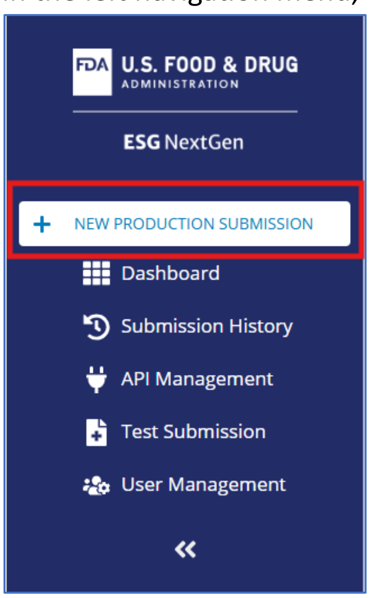
- If corrections to any field above e-Signature needs to be made after e-signing, click ‘Clear Signature’ to enable editing of the fields. Once corrections are made, the submission will need to be e-signed again.

10. Once all fields are completed and reviewed, click ‘Submit’ to complete the process of uploading a Production Submission.



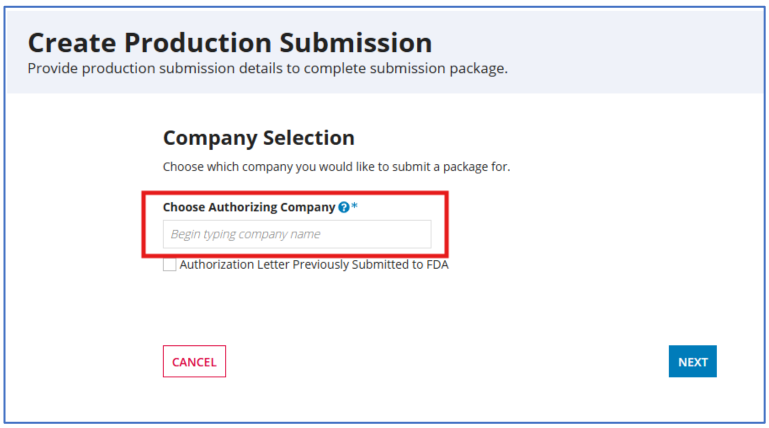
5.7 Production Submissions for Agents, CROs, or Consultants with a New Company in ESG NextGen

1. Log into ESG NextGen USP.
2. In the left navigation menu, click on ‘New Production Submission’.

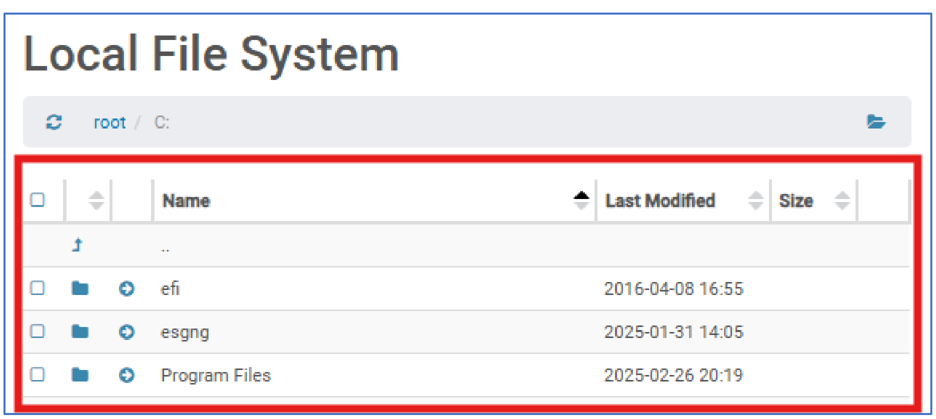


3. Begin typing the company name in the ‘Choose the Authorizing Company’ box to auto search and select the Authorizing Company the submission is being uploaded on their behalf.

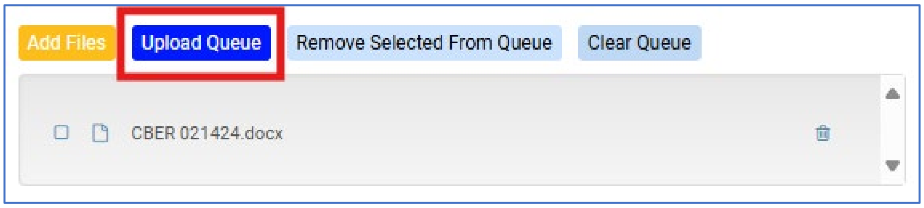
- This dropdown is populated by the Authorization Letters which have been uploaded into ESG NextGen. The uploaded Authorization Letters can be viewed in User Management by Power Users. For more information on User Management, refer to Section 7 User Management.
- If an Authorization Letter has never been submitted to the FDA for the company the submission is for, proceed to User Management to upload the Authorization Letter. For more information on User Management, refer to Section 7 User Management.



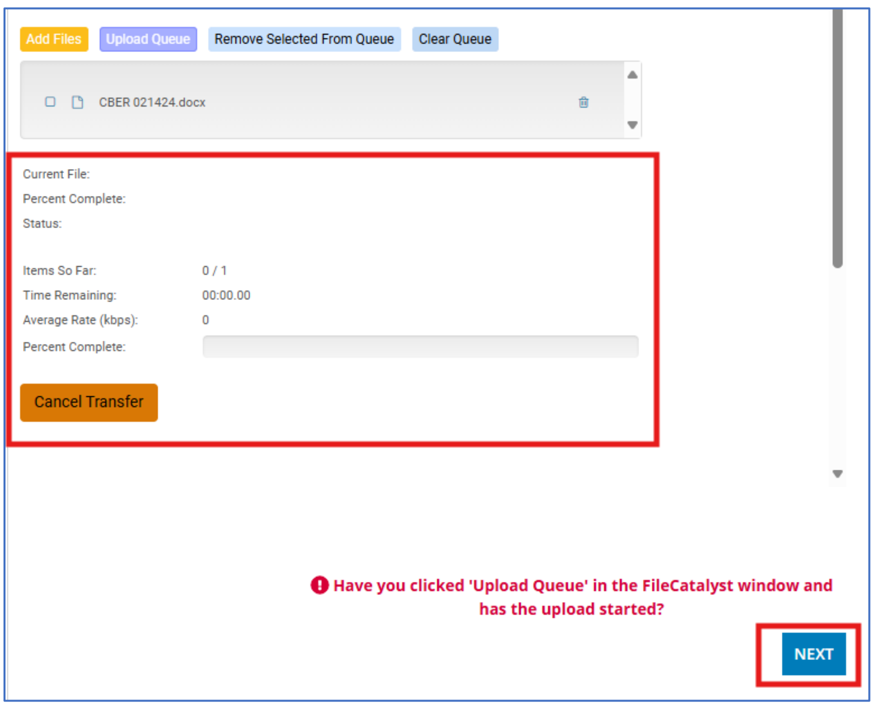
4. Once the company the user is submitting on behalf of is selected or entered, click ‘Next’.
5. The File Catalyst TransferAgent window will appear.
    - If this is your first submission via ESG NextGen USP, you will be prompted to download FileCatalyst Transfer Agent. For more information on downloading FileCatalyst Transfer Agent, refer to Section 2 Getting Started with USP.
6. Through the FileCatalyst Transfer Agent window, navigate to your file within your Local File System.



7. Select the file(s) to be uploaded and click Upload Queue.



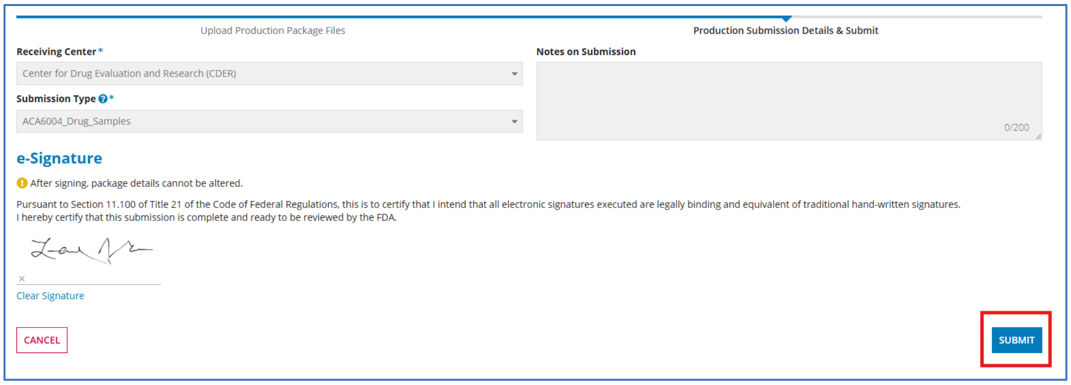
8. Once the upload has started, click 'Next'.
    - Note: The upload will continue in the background and complete without remaining on the page. For larger file uploads, do not wait on this page for the upload to complete. The USP will log users out after 20 minutes of inactivity. If a new submission has not proceeded to the next page and the 'Submit' button has not been clicked, the system will cancel the submission.



9. On the Production Submission Details & Submit page, complete the details of the submission.
    - Select the Receiving Center.
    - Select the Submission Type.
    - Notes of Submission is an optional field and can be used to provide additional details around the submissions. This information is not passed on to the Centers. It is a reference field for the submitter.
    - Electronically sign the submission by drawing your signature in the field with your mouse, finger, or stylus pen. This field is referred to as e-Signature.

- If corrections to any field above e-Signature needs to be made after e-signing, click ‘Clear Signature’ to enable editing of the fields. Once corrections are made, the submission will need to be e-signed again.

10. Once all fields are completed and reviewed, click ‘Submit’ to complete the process of uploading a Production Submission.



6. Tracking Submissions

6.1 Acknowledgements

Acknowledgements (ACKS) are sent to users by ESG NextGen as part of the processing of the submission via ESG NextGen. USP and API submissions (test and production) will receive ACK messages via email. Please retain these emails as your copy of the ACK message for future reference. The ACK messages are also viewable within the USP in Submission History. For more information on Submission History, refer to Section 6.2 Submission History.

ACK Number	ACK Purpose
ACK1	Provides information on the submission and if the submission was uploaded into ESG NextGen Success: Upload to ESG NextGen completed Failure: Due to a file failing the virus scan Failure: Due to not all files uploading to ESG NextGen
ACK2	Provides information on the submission and if the submission was successfully transmitted to the Center • Success: Submission was successfully transmitted to the Center • Failure: Submission exceeds the submission size guidelines set by the Center (see Center Submission Types)
ACK3/ACK4	Provides the Center’s response on the submission

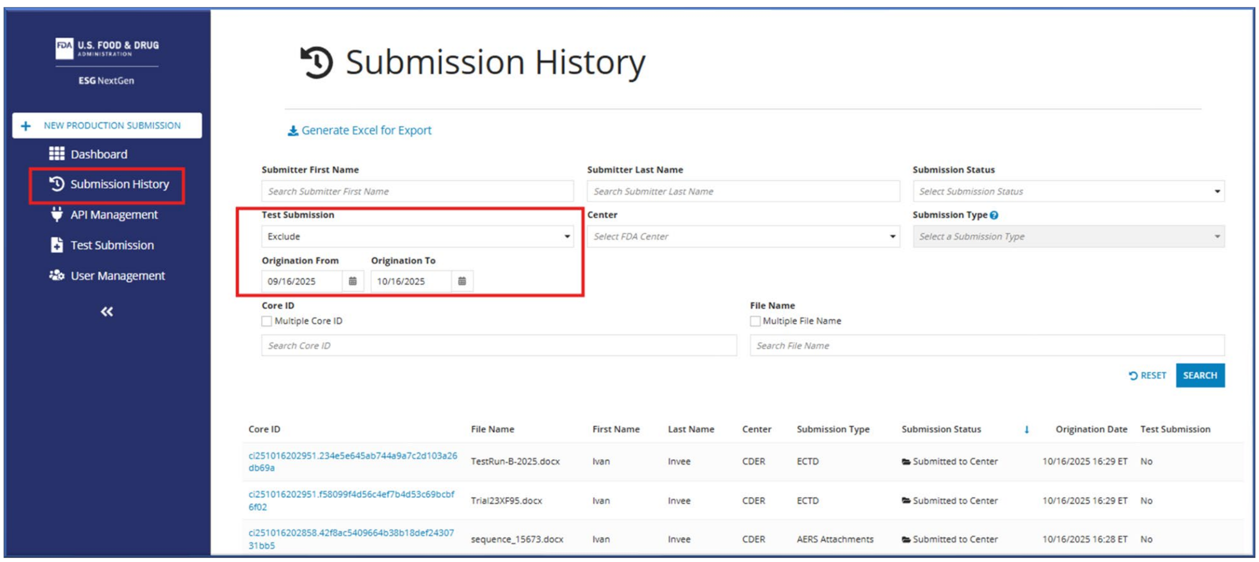
Not all submission types receive the same number of acknowledgments. Please reference the Submission Acknowledgements page to understand the different ACK messages sent per Center/Submission Type.

6.2 Submission History

6.2.1 Viewing Submission History Results, Filtering, and Exporting

Submission History allows for viewing and searching for test and production submissions. Users can search, filter, and review past submissions to ensure compliance and track progress.

1. Log into ESG NextGen USP.
2. In the left navigation menu, click 'Submission History'.



Information Available in Submission History:

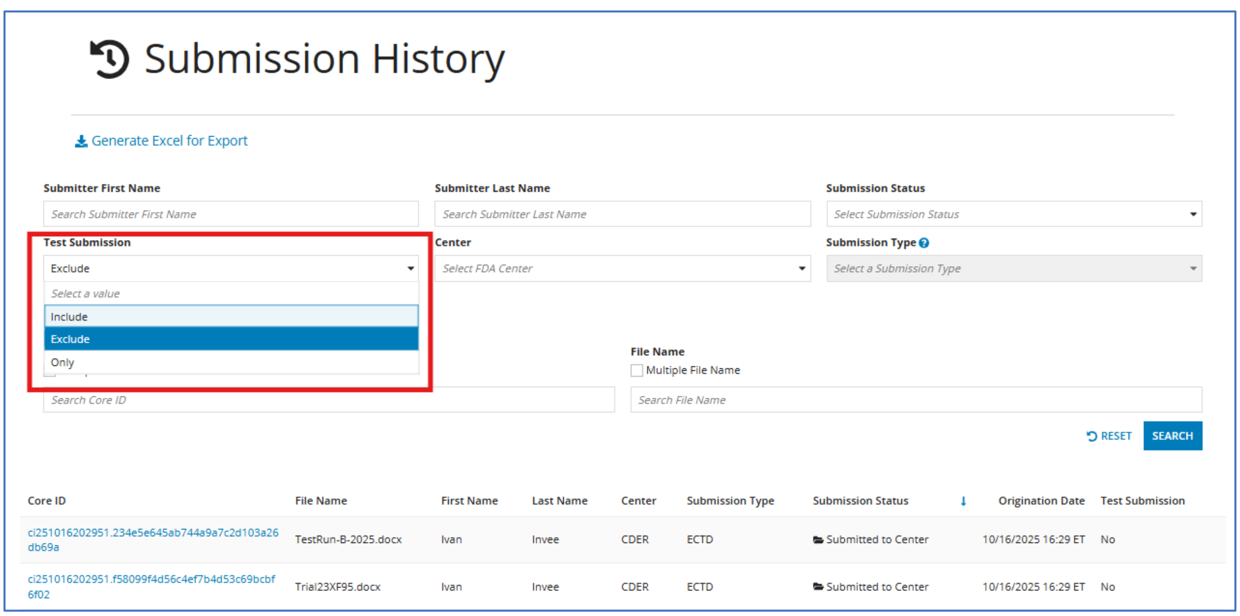
- Core ID
  - Unique ID assigned to each submission by ESG NextGen.
- File Name
  - The name of the file uploaded within the submission.
- Submitter's First and Last Name
  - The name of the person who uploaded the submission.
- Company
  - Displays only for Agents, CROs, and Consultants.
  - Displays the name of the Company the submission was submitted on behalf of.
- Center

- The Center the submission was uploaded to.
- Submission Type
  - The Submission Type for the Center the submission was uploaded to.
- Submission Status
  - Provides the most recent status of the submission.
- Origination Date
  - The date the submission was initiated within ESG NextGen.
- Test Submission
  - Indicates if the submission was a Test Submission.

Submission History allows for users to filter on any of the fields outlined above. The default filter criteria excludes Test Submissions and displays submissions for the past 30 days. To view submissions greater than 30 days, update the Origination From and Origination To dates to be for the time period needed.

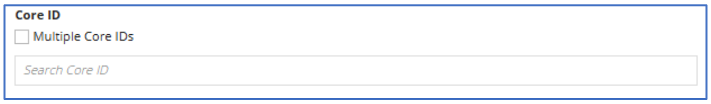
Users with the role of Submitter will only be able to see their own submission within Submission History.
Users with the role of Power User will be able to see all submissions uploaded from their company.

If a user needs to view their Test Submissions, the Test Submission filter will need to be updated to ‘Include’ Test Submission results with the Production Submission results or updated to ‘Only’ show Test Submission results.

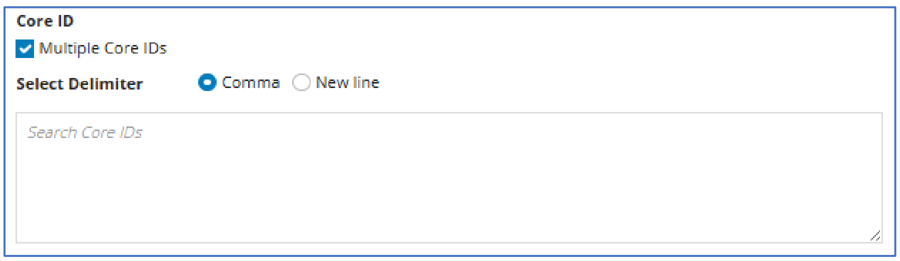


Users can search on a single Core ID or Multiple Core IDs as well as single and multiple file names.

Single Core ID search:



Multiple Core ID search:

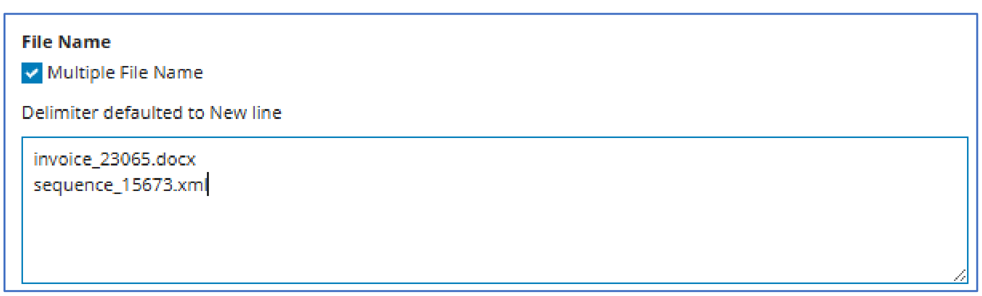


With a multiple Core ID search, users will have to select the delimiter which will separate each Core ID included in the search. A comma can be used to separate each Core ID or the Core IDs can be on their own lines within the entry box.

Users can search on multiple file names.

Single File Name search:

Multiple File Name search:

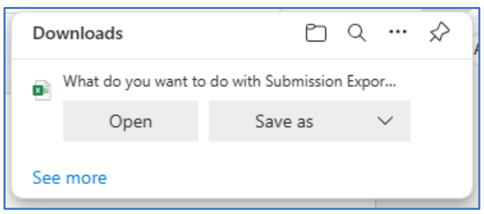


When entering the file names, each file name must be on its own line in the text box.

To export the search results of Submission History:

1. Click on 'Generate Excel for Export'.
    - ESG NextGen will compile the data and prepare it to be able to be downloaded.

2. Click on 'Download Export'.
    - The download will be available and the user can open the download from their web browser.



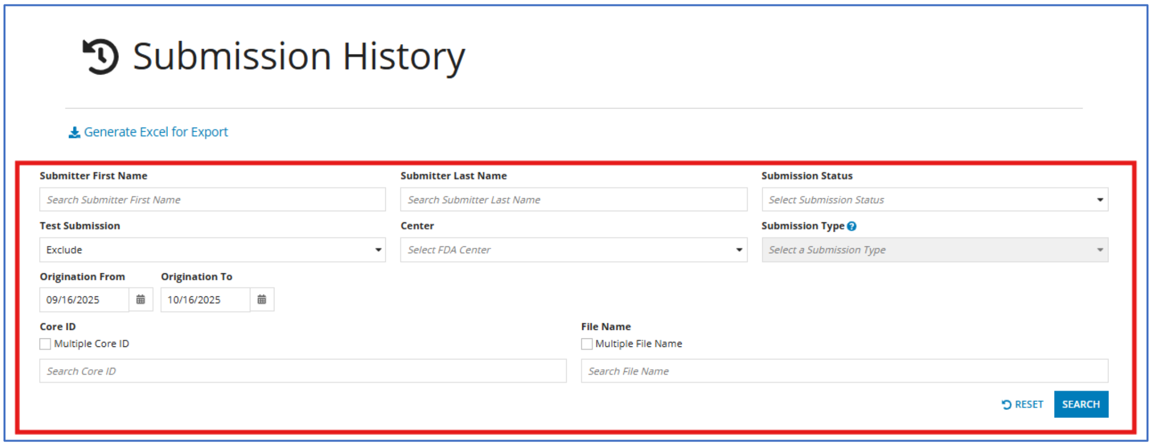
If a new search is generated within Submission History which is to be exported, the user must click the refresh icon to the left of Download Export to generate the new export. Once refresh is clicked, follow steps one and two outlined above.

6.2.2 Viewing an Individual Submission

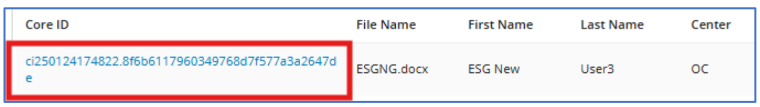
Submission History allows users to view additional details on each submission, outside of what is presented in the Submission History grid results.

To view an Individual Submission:

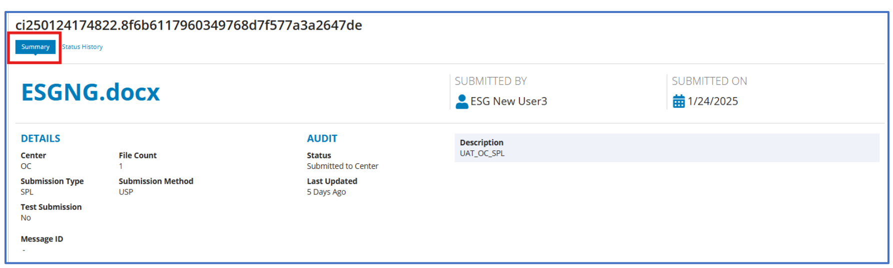
1. Utilize the filter options at the top of Submission History to narrow down the Submission History results to allow for finding the submission needing to be viewed.



2. Click on the blue Core ID link.

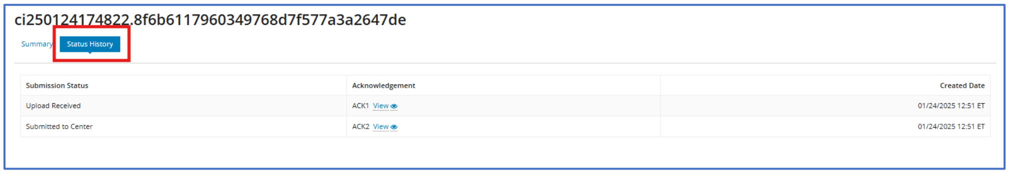


3. A new tab will open in the web browser which will provide additional details pertaining to the submission/Core ID selected.
   - **Summary:** This tab provides information pertaining to the submission such as the file name, file count, submission method for how the submission was loaded to ESG NextGen, and allows the user to view any information provided in the Description during upload



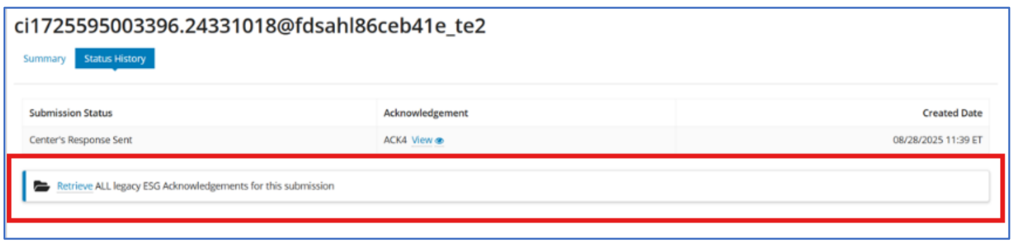
   - **Status History:** This tab provides the date/time of each Submission Status for the submission as well as allows the user to view the Acknowledgement messages.

     Acknowledgements where ESG NextGen sent the Acknowledgement message to the user, will appear in the grid/box. Users will be able to view the ACK1 and ACK2 messages and download the ACK3 message.



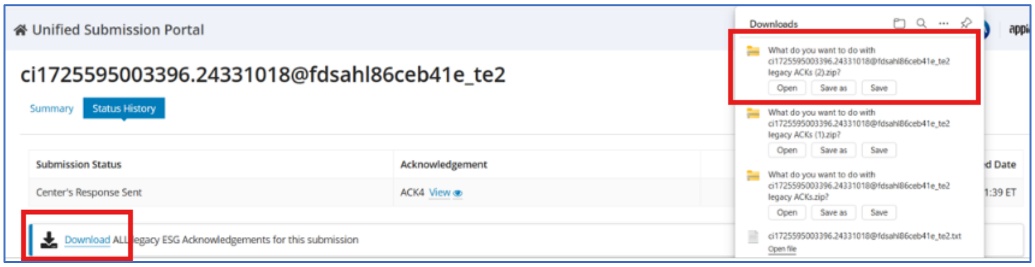
Acknowledgements where legacy ESG sent the Acknowledgement message to the user, there will be message under the grid/box stating ‘Retrieve ALL legacy ESG Acknowledgements for this submission’.

To start the download of legacy Acknowledgement messages, click on ‘Retrieve’.



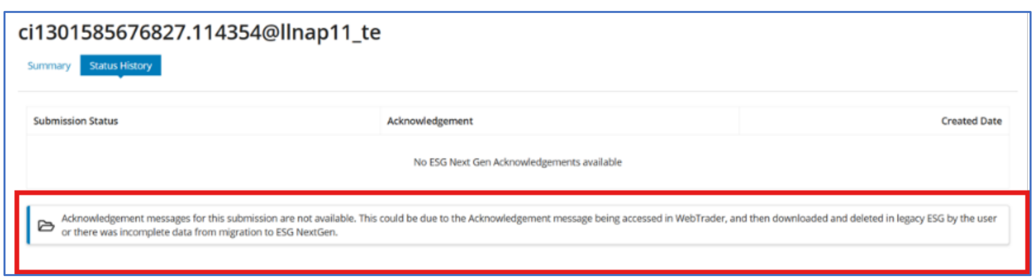
Once the system retrieves the legacy Acknowledgment messages, the message will update to be ‘Download ALL legacy ESG Acknowledgements for this submission.

Click on ‘Download’ to download the Acknowledgement messages. Follow your PCs prompts to Open/Save the file.
The file name will be the submissions Core ID followed by ‘legacy ACKs’
All Acknowledgements for the submission will be contained in the downloaded file.



There may be scenarios where the system is unable to return legacy Acknowledgement messages. This could be due to the Acknowledgement messages being accessed in WebTrader and then marked to be deleted or due to incomplete data from migration to ESG NextGen. If this occurs, the following message will display under the grid/box:
‘Acknowledgement messages for this submission are not available. This could be due to the Acknowledgement message being accessed in WebTrader, and then downloaded and deleted in legacy ESG by the user or there was incomplete data from migration to ESG NextGen.’

If this message is received, Acknowledgement messages for the submission are not available.

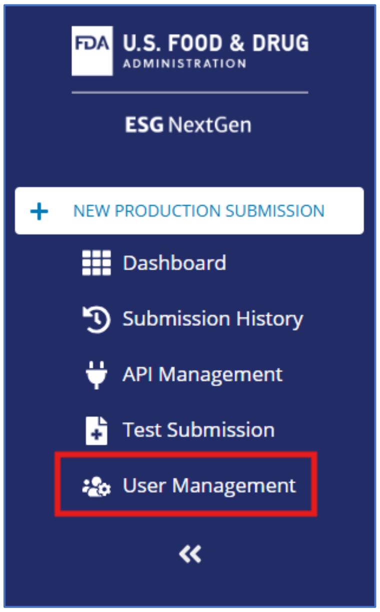


7. User Management

ESG NextGen provides user management functionalities within the USP. The User Role assigned to a user will determine the functionality available to the user within User Management.

To access User Management

1. Log into ESG NextGen USP.
2. In the left navigation menu, click on ‘User Management’.



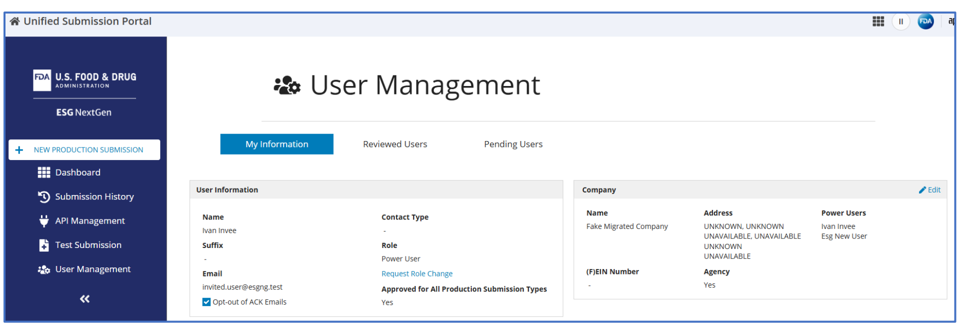
The Submitter Role has different tabs available than the Power User Role. Both roles will be described in this section.

7.1 My Information

Once User Management is chosen, the My Information tab is available. My Information is where users will go to view their user information and their company.

7.1.1 My Information for users with the Submitter role

Users with the Submitter Role will only have the My Information tab accessible. The My Information tab within ESG NextGen USP provides the user with a view of their User Information as well as their Company information.



7.1.1.1 User Information for Submitter Role

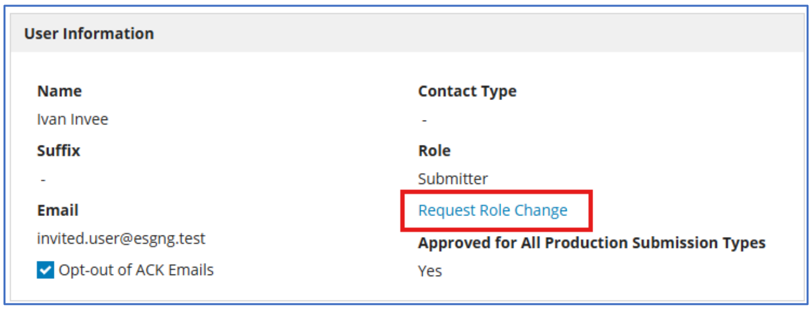
The User Information box on the left displays the user’s demographic information entered during the registration process.

Within the User Information box, users are able to determine if their account is approved for all production submission types. For more information on when test submissions are required, refer to Section 5.4 When to do a Test Submission.

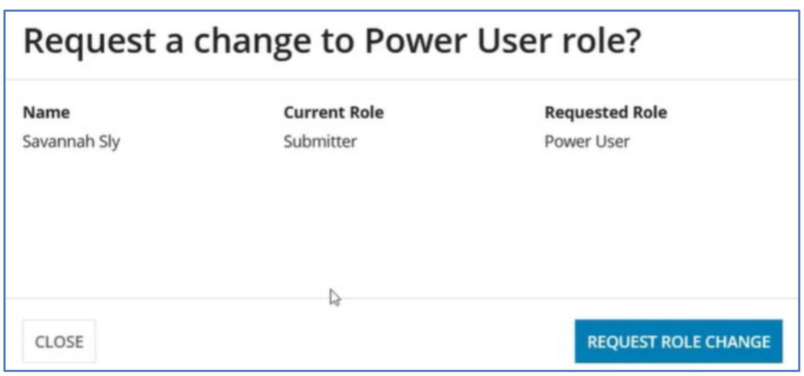
If a user does not wish to receive Acknowledgement messages via email for USP and API submissions, users can check the ‘Opt-out of ACK emails’. To start receiving Acknowledgement messages via email again, users can uncheck the ‘Opt-out of ACK emails’. By default, all users are Opted In to receiving Acknowledgement messages via email.

To change User Role

1. Click ‘Request Role Change’ within the User Information box.

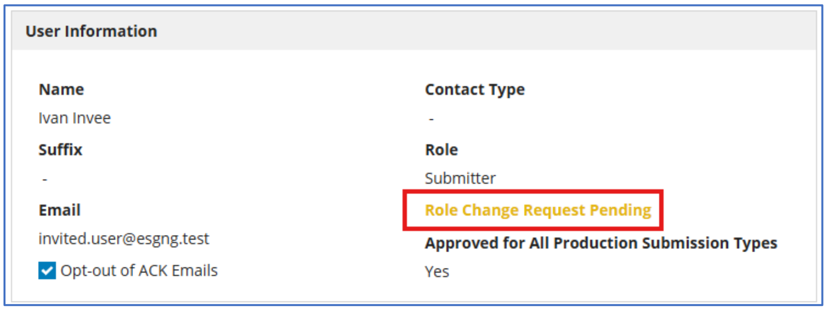


2. ‘Request a change to Power User role?’ pop-up box will appear.
   - The box will display the user is requesting to change their user role from Submitter to Power User.



3. To submit the request, click ‘Request Role Change’.
4. To cancel the request, click ‘Close’.
5. Once the role change request is submitted, the request will be reviewed and approved/declined by a Power User of the Company.
   - While the request is pending:
     - The User Information box will display ‘Role Change Request Pending’.
     - The user will retain functionality of a Submitter.

- If the request is approved, the user will have all Power User functionality within ESG NextGen USP.
- If the request is declined, the user will retain Submitter privileges.
- An email will be sent to the user notifying them of the results of their role change request.

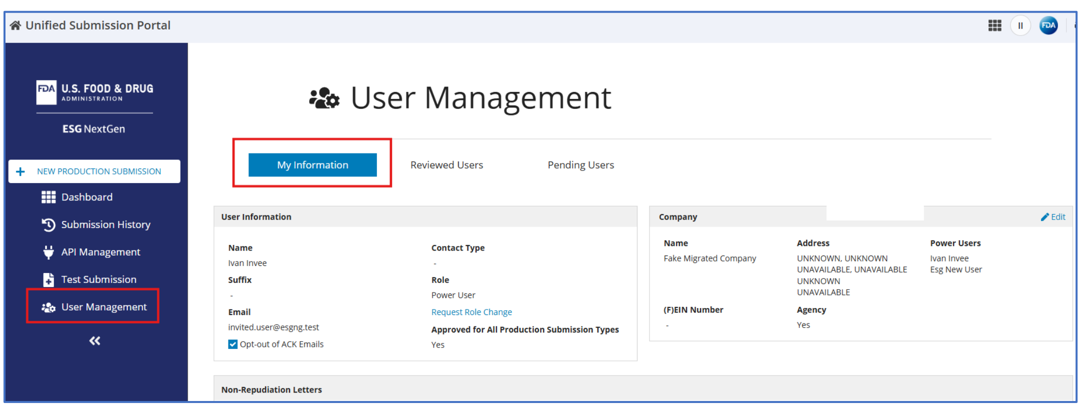


7.1.1.2 Company

Company displays information pertaining to the Company the user is registered under. Submitters have view only rights to Company.

7.1.2 My Information for users with the Power User role

The My Information tab within ESG NextGen USP provides Power Users with a view of their User Information, Company Information, Non-Repudiation Letters, and Authorization Letters. Authorization Letters are required for companies which indicated they are an Agency and have Agents, CROs, or Consultants submitting on behalf of other companies.



7.1.2.1 User Information for Power User Role

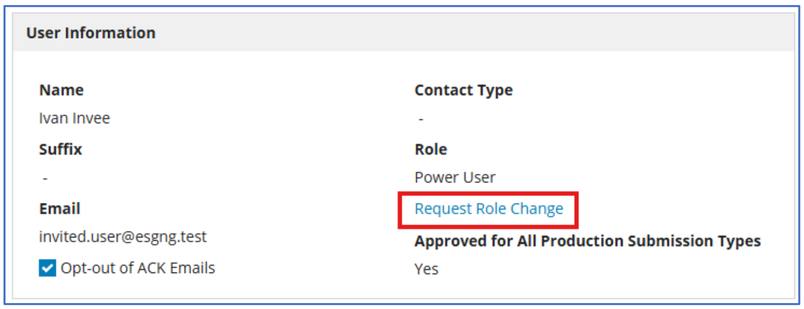
The User Information box within the My Information tab displays the user's demographic information entered during the registration process.

Within User Information, users are able to determine if their account is approved for all production submission types. For more information on when test submissions are required, refer to Section 5.4 When to do a Test Submission.

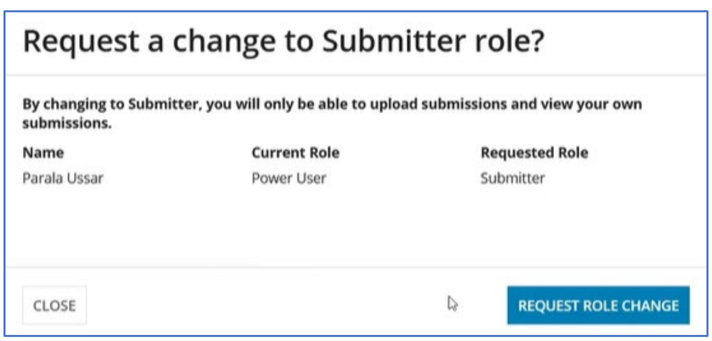
If a user does not wish to receive Acknowledgement messages via email, users can check the 'Opt-out of ACK emails'. To start receiving Acknowledgement messages via email again, users can uncheck the 'Opt-out of ACK emails'. By default, all users are Opted In to receiving Acknowledgement messages via email.

To change User Role

1. Click 'Request Role Change' within the User Information box.
    - Note: This option is only available if there are more than one Power Users for the Company.
        - If there is only one Power User for a company, a user with the Submitter role will need to be changed to a Power User.



2. 'Request a change to Submitter role?' pop-up box will appear.
    - The box will display the user is requesting to change their user role from Power User to Submitter. A notification is displayed letting the user know by making this change, the user will only be able to upload submissions and view their own submissions.



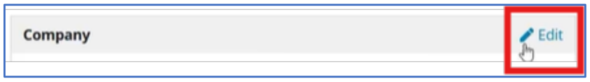
3. To submit the request, click 'Request Role Change'.
4. To cancel the request, click 'Close'.
5. Once the role change request is submitted, the user's role will automatically change from Power User to Submitter.

7.1.2.2 Company

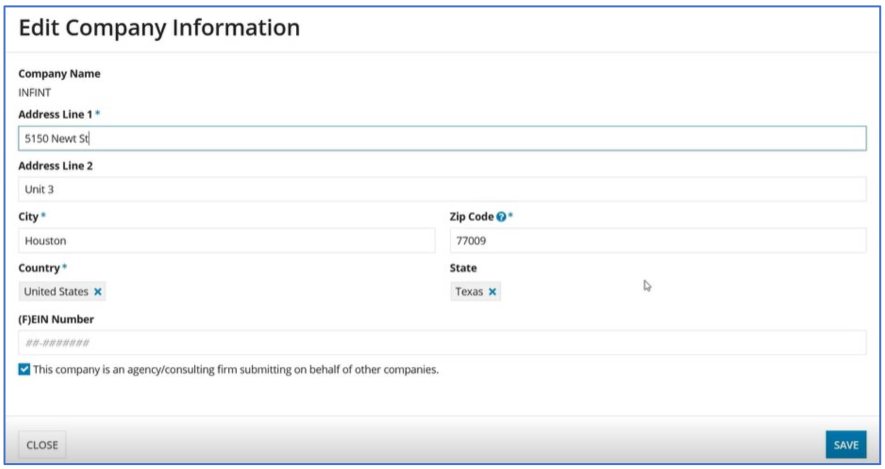
Company displays information pertaining to the Company the user is registered under.

To Edit Company Information

1. Click 'Edit' in the upper right-hand corner of the Company box.



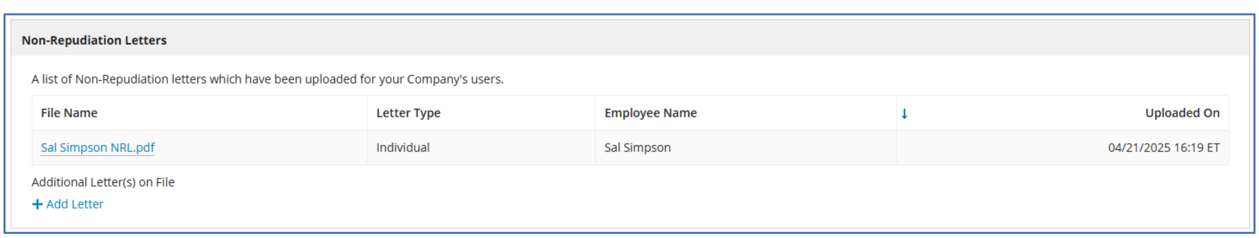
2. The 'Edit Company Information' box will appear.
    - Note: Company Name is not editable.
3. Once all edits are complete, click 'Save'.
4. To cancel edits, click 'Close'.



7.1.2.3 Non-Repudiation Letters

Power Users for a company will be able to view all the Non-Repudiation Letters which have been uploaded in the USP for their company and they will be able to upload new Non-Repudiation Letters.

- Note: Users migrated to ESG NextGen from legacy ESG have Non-Repudiation Letters stored outside of ESG NextGen.



Non-Repudiation Letters

A list of Non-Repudiation letters which have been uploaded for your Company's users.

File Name	Letter Type	Employee Name	↓ Uploaded On
Sal Simpson NRL.pdf	Individual	Sal Simpson	04/21/2025 16:19 ET

Additional Letter(s) on File

+ Add Letter

By clicking on the file name, Power Users will be able to view the .pdf (PDF) files within the USP. Non-PDF files will download to allow the Power User to view.

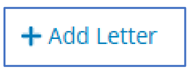
Company-wide Non-Repudiation Letters cover all employees for the company and the Employee Name field will be blank since this letter covers all employees.

Individual NRLs will display within the Employee Name column the name of the employee who uploaded the NRL and whom the NRL is for.

Individual Non-Repudiation Letters cover only the employee who is named in the Non-Repudiation Letter. If an employee will be covered under an Individual Non-Repudiation Letter, the employee will upload their Individual Non-Repudiation Letter during their registration for a ESG NextGen USP account. A Power User always has the ability to upload letters if necessary.

Uploading a Non-Repudiation Letter

1. In the Non-Repudiation Letters box, click '+ Add Letter'.

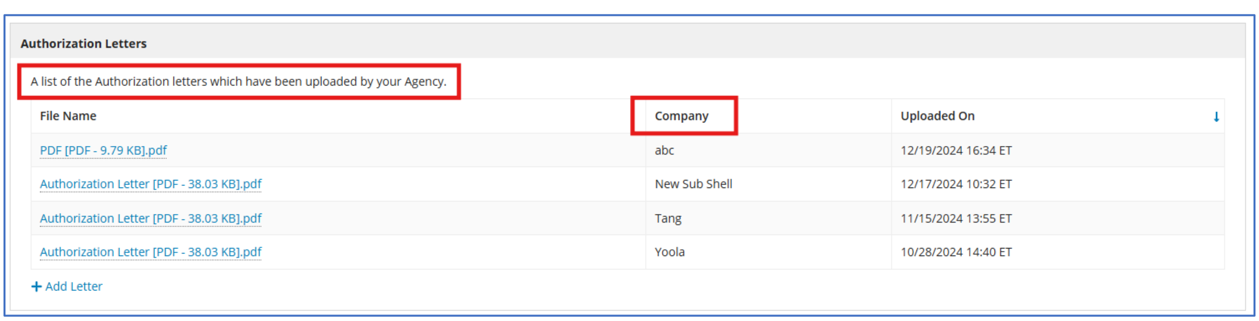


2. 'Upload Non-Repudiation Letter' box will be available.

3. Select whether the Non-Repudiation Letter being uploaded is a company-wide or individual Non-Repudiation Letter.
4. Click 'Upload / Drop file here' to select the Non-Repudiation Letter to upload.
5. Click 'Upload' to upload the letter.
6. Click 'Cancel' to cancel the upload of the letter.

7.1.2.4 Authorization Letters

Power Users for a company will be able to view and upload the Authorization Letters for their agency. The grid will display which company each Authorization Letter is for.



Authorization Letters

A list of the Authorization letters which have been uploaded by your Agency.

File Name	Company	Uploaded On
PDF [PDF - 9.79 KB].pdf	abc	12/19/2024 16:34 ET
Authorization Letter [PDF - 38.03 KB].pdf	New Sub Shell	12/17/2024 10:32 ET
Authorization Letter [PDF - 38.03 KB].pdf	Tang	11/15/2024 13:55 ET
Authorization Letter [PDF - 38.03 KB].pdf	Yoola	10/28/2024 14:40 ET

+ Add Letter

- Note: Users migrated to ESG NextGen from legacy ESG have Authorization Letters stored outside of ESG NextGen.

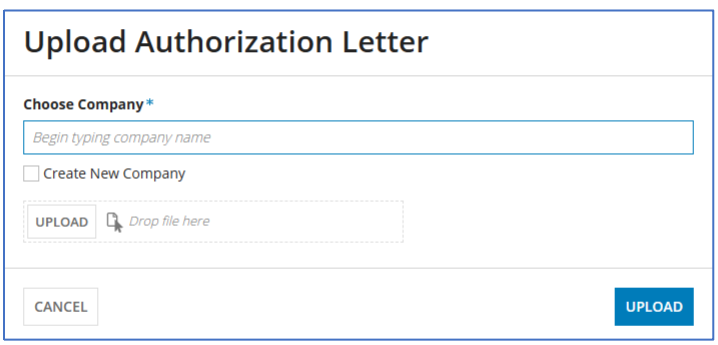
Power Users for companies which utilize an Agent/CRO/Consultant to upload files on their behalf, will be able to view the Authorization Letter(s) which have been uploaded for their company. They will not have access to add Authorization Letters as they are not an agency.

By clicking on the file name, Power Users will be able to view the .pdf (PDF) files within the USP. Non-PDF files will download to allow the Power User to view.

Uploading an Authorization Letter

1. In the Authorization Letters box, click '+ Add Letter'.

2. 'Upload Authorization Letter' box will be available.



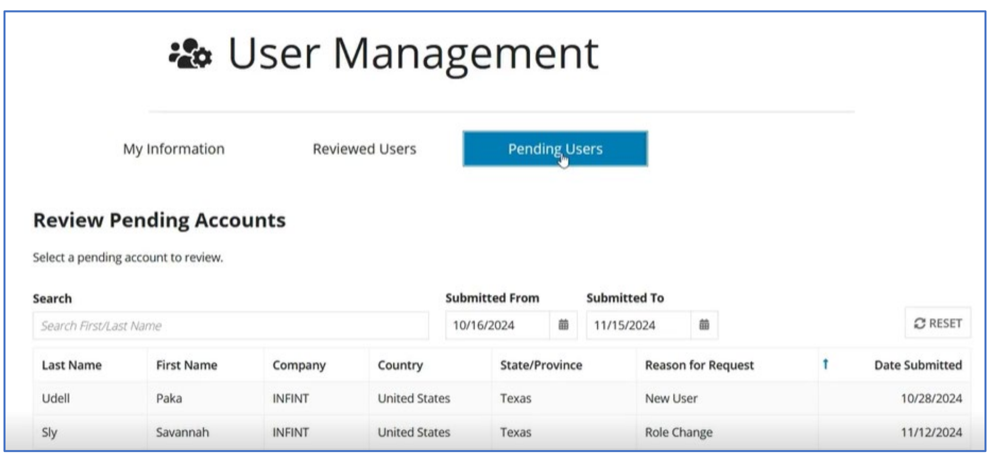
3. Start typing the company name the Authorization Letter is from in the 'Choose Company' box.
   - If the company is found, select the company.
4. If the company is NOT found in the 'Choose Company' box, check 'Enter a new company'.

5. Enter the company's name in the 'Company Name' box.
6. Click 'Upload / Drop file here' to select the Authorization Letter to upload.
7. Click 'Upload' to upload the letter.
8. Click 'Cancel' to cancel the upload of the letter.

Note: To be able to upload Authorization Letters, the company must be marked as an Agency and the user must be a Power User.

7.2 Pending Users

The Pending Users tab is available to Power Users of the company. Pending Users will display the users who need their account reviewed due to newly registering for ESG NextGen or for requesting a role change.



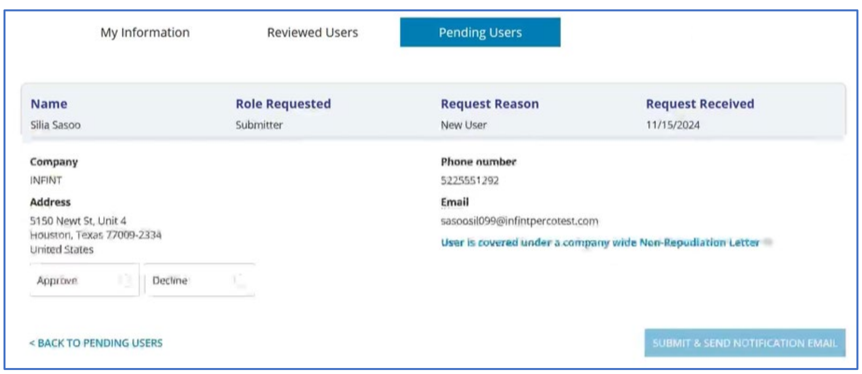
Power Users are able to search by First/Last Name of pending users. The filter criteria defaults to filter on the last 30 days. Power Users are able to update the Submitted From and Submitted To dates to further refine their search.

Once an action is taken on a Pending User, the user can be found on the Reviewed Users tab.

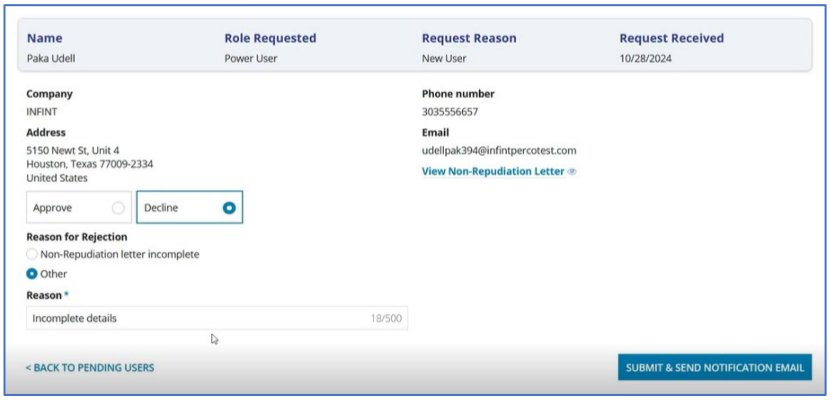
7.2.1 Reviewing a New User Request

1. Click on the row of the user to review.

2. The user's information will appear.
   - The box will contain the new user's name, the user role they have requested, the reason for their request, and the date of their request.
   - Additional information pertaining to user and the company are present.
   - If the company has a company-wide Non-Repudiation Letter, the system will state that along with a link to view the letter.
   - If an individual Non-Repudiation was uploaded during registration, the system will display a link to view the individual letter.



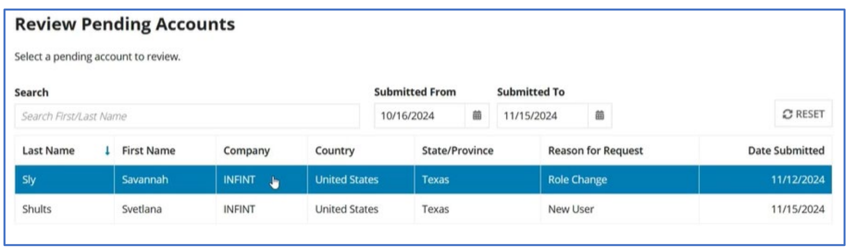
3. To approve the registration, click 'Approve'.
4. To decline the registration, click 'Decline'.
   - A 'Reason for Rejection' must be supplied.
     - If 'Other' is selected, type the reason in the box provided.



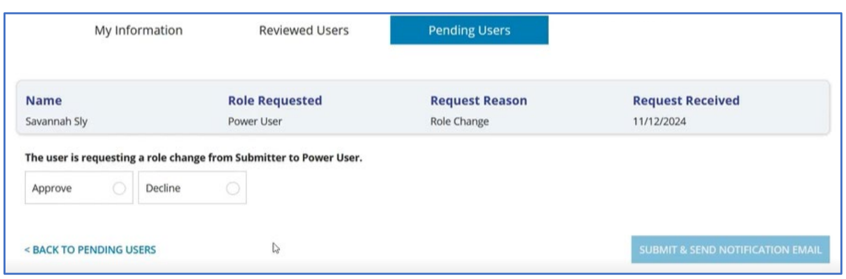
5. To finalize the review of the new user registration, click ‘Submit & Send Notification Email’.
    - This will update the system on the decision made and send an email to the new user informing them of the status of their registration.
6. Selecting the ‘<Back to Pending Users’ option will return the Power User to the main Pending User screen.

7.2.2 Reviewing a Role Request Change

1. Click on the row of the user to review.



2. The user’s information will appear.
    - The box will contain the users name, the role requested, the request reason, and the date of their request.

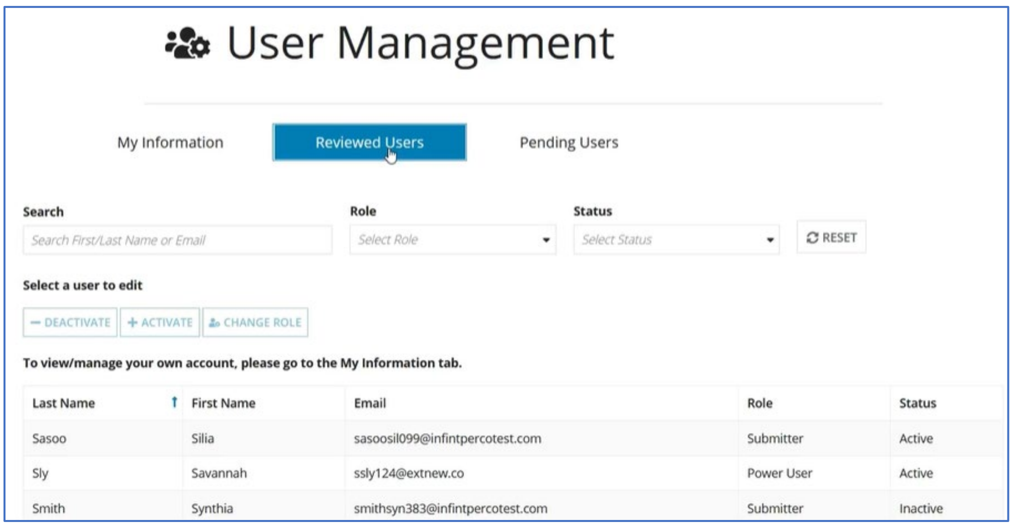


3. To approve the role change request, click ‘Approve’.
4. To decline the role change request, click ‘Decline’.

5. To finalize the review of the new user registration, click ‘Submit & Send Notification Email’.
    - This will update the system on the decision made and send an email to the user informing them of the status of their role change request.
6. Selecting the ‘<Back to Pending Users’ option will return the Power User to the main Pending User screen.

7.3 Reviewed Users

The Reviewed Users tab is available to Power Users of the company. Reviewed Users allows Power Users to find the status (active/inactive) of a user, to deactivate a user, activate user, and change a user’s role.



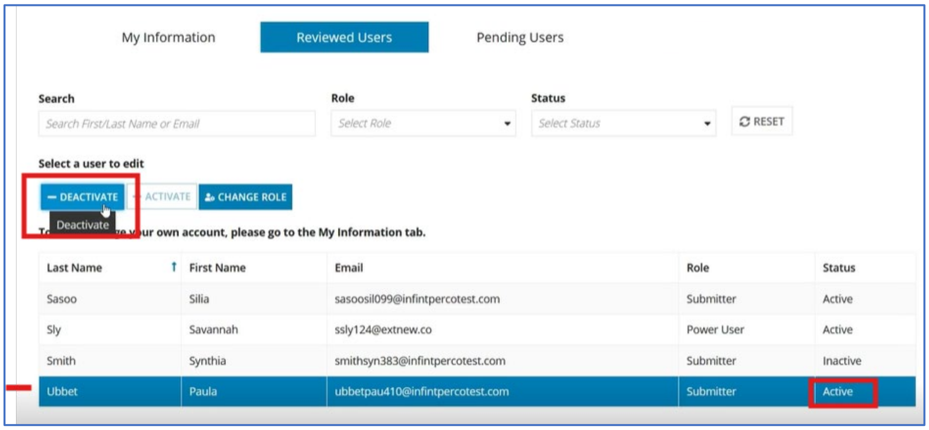
Power Users are able to search by First/Last Name, Role, and Status of users. All users for the company whose registrations have been approved or declined will display in Reviewed Users.

- Note: The account for the Power User logged in utilizing the USP, will not display within Reviewed Users. Logged in users will manage their account from their own My Information tab.

7.3.1 Deactivating a User

Deactivating a user will cause the user to no longer have access to ESG NextGen.

1. Click on the row of the Active user to deactivate.
2. Click on the ‘-Deactivate’ option at the top of the list of users.



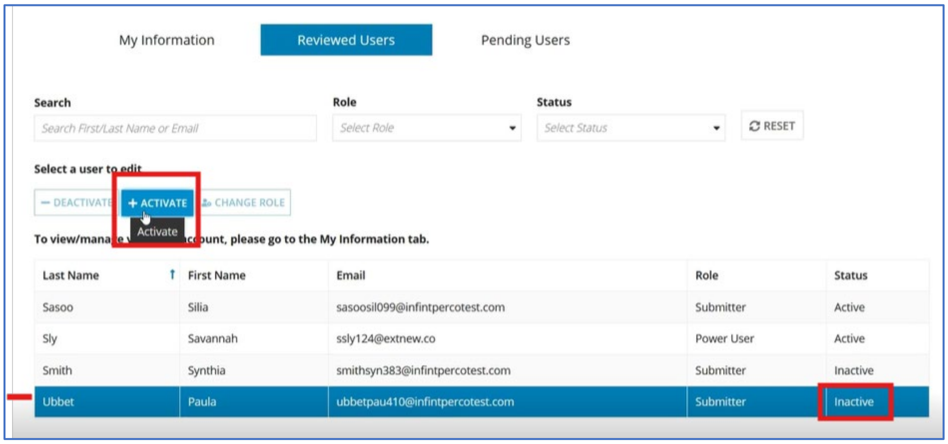
3. A confirmation box will appear asking ‘Are you sure you want to deactivate the following user?’.

4. To deactivate the user, click ‘Deactivate’.
    - An email notification will go to the user informing them their account has been deactivated.
5. To cancel the action, click ‘Close’.

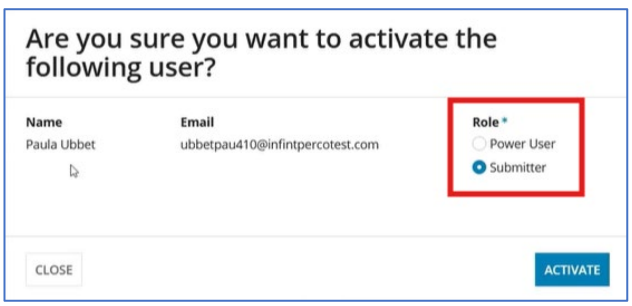
7.3.2 Activating a User

Activating a user account will update the user’s status to Active and allow the user to log in and access ESG NextGen.

1. Click on the row of the Inactive user to activate.
2. Click on the ‘+Activate’ option at the top of the list of users.



3. A confirmation box will appear asking 'Are you sure you want to activate the following user?'.
   - The role is defaulted to the user's last role while active within ESG NextGen.
   - If the user's role needs to be updated, it can be done here by selecting the circle to the left of the role the user will need.

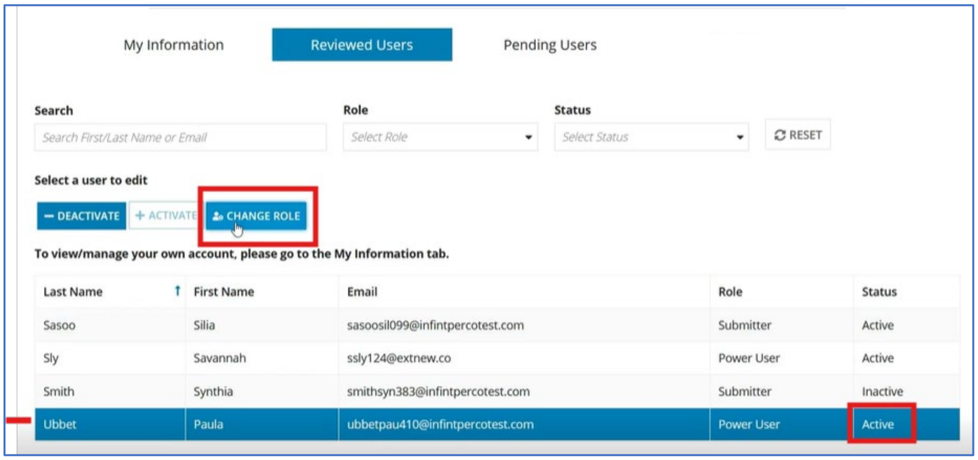


4. To activate the user, click 'Activate'.
   - An email notification will go to the user informing them their account has been reactivated.
5. To cancel the action, click 'Close'.

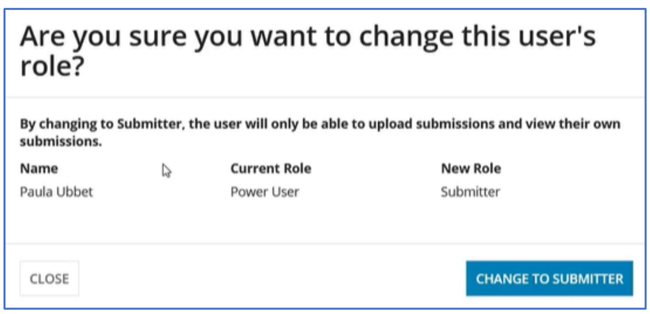
7.3.3 Changing the Role of a User

Changing a user's role, will update their role from Submitter to Power User or Power User to Submitter.

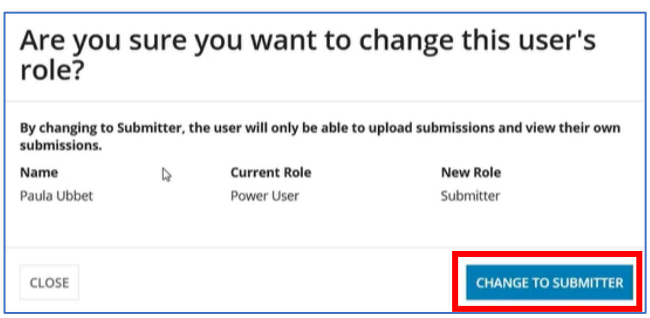
1. Click on the row of the Active user to change their role.
2. Click 'Change Role'.



3. A confirmation box will appear asking ‘Are you sure you want to change this user’s role?’.
   - ESG NextGen will auto populate the New Role based on what role the user is currently assigned.



4. To change the user’s role, click ‘Change to Submitter’ or ‘Change to Power User’.
   - An email notification will go to the user informing them their user role has been changed.



5. To cancel the action, click ‘Close’.

8. User Support and Troubleshooting

ESG NextGen provides multiple support avenues to help users address common issues, troubleshoot problems, and resolve errors encountered during the submission process. This section outlines how to access support and provides troubleshooting tips.

8.1 Accessing ESG NextGen Support

For technical issues or general inquiries, please contact ESG NextGen Support at:

- Email: ESGNGSupport@fda.hhs.gov

ESG NextGen Support is available Monday – Friday, 8 AM ET to 8 PM ET.

When contacting ESG NextGen Support regarding an issue encountered, please be sure to include:

- A detailed description of the issue, including steps taken.
- Any error messages encountered.
- Core ID for the submission.
- Screenshots, if applicable.

8.2 Troubleshooting Tips

Potential Issue	Troubleshooting Tips
Unable to log in	• Verify correct email address is being used. • Check spam folder for one-time passcode email. • Reset password.
FileCatalyst Transfer Agent fails to install	• Ensure system requirements are met (see Section 2.2). • Contact ESGNGSupport@fda.hhs.gov
File Upload Failure	• Confirm network connectivity. • Do not turn off PC while files are uploading.
Power User unable to see some of the company users within User Management	• Confirm the company the user is registered with. ○ Note: Slight variations in a company's name will result in a separate company being created.

Received an ACK1 or ACK2 Failure	• Refer to the Acknowledgement message for tips to resolve. • View Center submission size thresholds Center Submission Types – page to be updated 4/14/25

9. Additional Training Resources

The ESG NextGen website contains additional training materials and resources to guide users through utilizing ESG NextGen.

Training videos are available at <insert link>.
The training videos cover registration, test and production submission, and user management.

All ESG NextGen user guides are available on the ESG NextGen website.

For additional information regarding API and AS2 submissions, please refer to their user guides which can be found here under User Guides:
ESG NextGen User Guide for API
ESG NextGen User Guide for AS2

10. Appendices

The appendices provide supplementary information to support users in understanding the ESG NextGen platform, including terminology and commonly used acronyms. This section serves as a quick reference for both new and experienced users.

10.1 Glossary of Terms

- **API (Application Programming Interface)**: A set of tools and protocols that allow software applications to communicate with ESG NextGen. APIs enable users to automate submissions and integrate their internal systems with the ESG NextGen platform.

- **AS2 (Applicability Statement 2)**: A protocol used for secure, point-to-point transfer of regulatory data to the FDA. AS2 allows for automated submissions through ESG NextGen.

- **Acknowledgment (ACK)**: An electronic receipt sent to users confirming their submission has been received, validated, or processed by ESG NextGen or the FDA.

- **Core ID**: A unique identifier assigned to each submission in ESG NextGen, used to track individual files or sets of files through the submission process.

- **FileCatalyst TransferAgent**: A tool required for all file submissions within ESG NextGen's Unified Submission Portal (USP). It ensures fast, secure, and reliable file transfers, supporting files up to 1TB.
- **Power User**: A user role in ESG NextGen with full administrative privileges, responsible for managing company users, submissions, and API credentials.
- **Submitter**: A user role in ESG NextGen who is authorized to submit regulatory files on behalf of their company and view their own submissions.
- **Unified Submission Portal (USP)**: The web-based interface of ESG NextGen that consolidates submission management, file uploads, and user management.

10.2 Acronyms

- **ACK**: Acknowledgment
- **API**: Application Programming Interface
- **AS2**: Applicability Statement 2
- **CRO**: Contract Research Organization
- **ESG**: Electronic Submissions Gateway
- **FCTA**: FileCatalyst Transfer Agent
- **FDA**: Food and Drug Administration
- **OTP**: One-Time Passcode
- **USP**: Unified Submission Portal