



### Electronic Submission Gateway (ESG) NextGen

User Acceptance Test Guide for Industry Users: Application Programing Interfaces

> V3.0 November 20, 2024



#### Table of Contents

1	Purpose	2
2	ESG NextGen Introduction	2
3	UAT Introduction	3
	3.1 UAT Schedule	3
	3.1.1 Wave 1: July 2024 – August 2024	3
	3.1.2 Wave 2: September 2024 - October 2024	3
	3.1.3 Wave 3: October 2024 - November 2024	4
	3.2 UAT Training and Support	4
4	Prerequisites to API Testing	4
	4.1 Install the PowerShell App	4
	4.1.1 From GitHub	4
	4.1.2 Using the Windows Package Manager Winget Command-line Tool	5
5	API File Submission	6
	5.1 Prepare Files	6
	5.2 Obtain API Client Id and Secret	7
	5.3 Update credentials.xml	9
	5.4 Update the XML File Path	9
	5.5 Execute the File Upload Script	10
	5.6 Executing API File Upload Script	10
	5.7 Check File Submission Status	14
A	ppendix 1. Common Troubleshooting Issues	15
	1.1 Versioning Mismatch	15
	1.2 Multiple Versions of PowerShell	16
	1.3 PowerShell Execution Policy	16
A	ppendix 2. FDA_Center and Submission Types	18
A	ppendix 3. API Specifications	20
A	ppendix 4. API Upload Test Cases	57
A	ppendix 5. Industry Partner APIs	58



## 1 Purpose

This User Acceptance Testing (UAT) guide is a supporting document for testers participating in the UAT of the Electronic Submission Gateway (ESG) Next Generation (ESG NextGen) Application Programing Interfaces (APIs). It introduces ESG NextGen and describes key ESG NextGen terms. This document, together with "UAT Testing Scripts for Industry Users, Unified Submission Portal (USP)" prepares and guides testers to conduct UAT for ESG NextGen.

# 2 ESG NextGen Introduction

ESG NextGen addresses some major pain points of the legacy ESG in user management, package preparation, and file submission. It also introduces new business processes and new technologies to streamline the submission process, enhance the user experience (UX) and improve security, as described below.

**Submission Package Preparation**: ESG NextGen modernizes the UX and replaces the legacy ESG User Interface (UI) with the new USP, which provides step-by-step guidance to prepare the submission package.

#### File Submission Improvements:

- ESG NextGen provides web service Application Programming Interfaces (APIs) to submit files and check submission status. The APIs enable companies to integrate FDA file submissions with their IT systems to achieve submission automation.
- ESG NextGen tracks the status of submissions via the USP, APIs, emails and FDA Acknowledgements.
- By leveraging modern cloud-based network technologies, ESG NextGen dramatically increases the file size upload capacity. In Release 1, The ESG NextGen can take up to a 1TB file submission. Further increases in file size will be developed in future ESG NextGen releases.

**File Submission Options**: ESG NextGen provides three interfaces for industry to submit files to FDA:

- **USP**: The USP was developed to address the business process integration, UX, self-service, and communication gaps of the legacy ESG. USP seamlessly integrates user registration, user account management, package preparation and submission, status tracking, reports and dashboards in a web-based UI with a modern look and feel, resulting in an a much-improved UX.
- **APIs**: ESG NextGen provides new web services APIs to submit files, check submission status and query other information. Companies can integrate these APIs with their systems to achieve submission and other business workflow automation.



• **Application Statement 2 (AS2)**: ESG NextGen will continue to support AS2, an electronic data interchange protocol that is used in the legacy ESG to submit files to FDA.

# **3 UAT Introduction**

ESG NextGen UAT is a critical phase in which participants are invited to test the endto-end functionalities of ESG NextGen and provide feedback on system function the APIs, their UX, performance and anything else on which they care to comment.

#### 3.1 UAT Schedule

The UAT will unfold in two waves, each targeting different functionalities within ESG NextGen. This manual outlines the testing schedule for each wave, and the API-related tasks in each wave.

#### 3.1.1 Wave 1: July 2024 – August 2024

In Wave 1, all users will need to set up new accounts in ESG NextGen to test the user registration process. See the step-by-step guide to registering new users in Module <u>ESG NextGen UAT Training video</u>.

Wave 1 tasks include:

- Test new user registration and user management features
- Test submissions via the USP
- Test submissions via APIs

#### 3.1.2 Wave 2: September 2024 - October 2024

In Wave 2, user accounts will be migrated from the legacy ESG to ESG NextGen. Testers who have accounts in the legacy ESG will receive an email notification with the additional account registration steps required to activate their accounts in ESG NextGen.

Wave 2 tasks include:

- Test submissions via AS2
- Test existing ESG user accounts migration
- Re-test improvements from UAT feedback in Wave 1



#### 3.1.3 Wave 3: October 2024 - November 2024

In Wave 3, legacy ESG data will be re-migrated into ESG NextGen.

Wave 3 tasks include:

- Test submissions via AS2, API, and/or USP
- Test existing ESG user accounts migration
- Review/test What's New items
- End to end testing with Centers

#### **3.2 UAT Training and Support**

**Frequent Asked Questions (FAQs):** UAT testers can check <u>ESG NextGen</u> <u>Frequently Asked Questions | FDA</u> for all FAQs related to ESG NextGen.

**UAT Training:** Demo videos, previous industry demo recordings, this UAT guide and UAT Testing Scripts are available at the <u>ESG NextGen UAT Landing Page</u>. The ESG NextGen team plans to hold UAT kickoff and training sessions before UAT starts.

**UAT Feedback Sessions**: During both the Wave 1 and Wave 2 UAT phases, the ESG NextGen team plans to host weekly sessions to demonstrate ESG NextGen functions, answer questions, and collect feedback from testers. A detailed schedule of the sessions will be announced during the UAT kickoff meeting.

**Technical Support**: UAT testers can email <u>esgngSupport@fda.hhs.gov</u> with questions or to request technical support. Please assist the ESG NextGen Support Team in diagnosing your issue by including in your email a detailed description of the issue, any error messages, and screenshots if applicable.

# **4** Prerequisites to API Testing

The ESG NextGen team has developed executable scripts that integrate ESG NextGen APIs to obtain user and company information, submit files into the system, and check submission status. To run these scripts, the PowerShell application needs to be installed. Users can use any of the methods listed below to install the PowerShell App in their machine.

#### 4.1 Install the PowerShell App

#### 4.1.1 From GitHub

a) Download the following PowerShell installation file from GitHub at <a href="https://github.com/PowerShell/PowerShell/releases/download/v7.4.2/PowerShell/releases/download/v7.4.2/PowerShell-7.4.2-win-x64.msi">https://github.com/PowerShell/PowerShell/PowerShell/releases/download/v7.4.2/PowerShell-7.4.2-win-x64.msi</a>



b) Double-click on the downloaded file and complete the PowerShell App installation process.



# Open the command line and type "pwsh" to validate the PowerShell app version (7.4.0 or newer) is installed properly.



#### 4.1.2 Using the Windows Package Manager Winget Command-line Tool

An alternative way to install PowerShell App is to use the Microsoft Windows winget package.

Notes:

- The Windows Package Manager winget command-line tool is available in Windows 11 and modern versions of Windows 10 as a part of the App Installer.
- If Admin privileges are required to install the PowerShell app using a winget package, contact your IT Support for assistance.
- a) Type "cmd" in Windows Search and open the Command Prompt window.
- b) Type the following command to search for the latest version of PowerShell.

#### winget search Microsoft.PowerShell

The output from the command will look like the following:

Name	ld	Version Source	
PowerSh	iell	Microsoft.PowerShell	7.4.1.0 winget
PowerShell Preview Microsoft.PowerShell.Preview 7.4.0.101 winget			

c) Type the following command to install PowerShell or PowerShell Preview using the id parameter.



winget install --id Microsoft.Powershell --source winget

winget install --id Microsoft.Powershell.Preview --source winget

# **5 API File Submission**

#### **5.1 Prepare Files**

 a) Download the ESGNG zip file (xml file, PowerShell scripts) from the <u>ESG</u> <u>NextGen UAT Landing Page</u> and extract the zip file to your local c:\ drive. This package includes all the files that are used for file submission via APIs.



Figure 1: Copying all test files c:\ESGNG drive

- b) If you want to test different file formats, add or modify the file formats.
- c) If you want to save PowerShell scripts in a different location, you will need to modify the scripts because the XML files are configured with the original path. The API script should be modified so the path directory for the api\_Upload.ps1 script points to the modified path location.



Figure 2. Copying all PowerShell script to desired location



#### 5.2 Obtain API Client Id and Secret

To use ESG NextGen APIs, users are required to obtain Client Id and Secret for authentication. A Power User of a company registered in ESG NextGen has the privilege to obtain the Client Id and Secret, using the following steps:

1. Sign into the <u>https://appian-uat-dsc.fda.gov/</u> with the Power User email and password.

<b>™ESG</b> NEXTGEN
EMAIL
PASSWORD
This is my device
Sign On
Change Password   Forgot Password
Don't have an account? Register now

Figure 3. Sign in to ESG Next USP

Check the Power User's email for the One Time Passcode (OTP) and enter it into the popup.



Figure 4. Enter OTP



Login to the ESG NextGen USP main page.



Figure 5. ESG NextGen home page

- d) Power Users have access to the API Management function. Click **API Management** in the left navigation bar
- e) Click Generate New to create a new set of Client Id and Secret.

	API Management Click to reveal credentials or to replace existing credentials.
™ESG	Your API Credentials
NEXTGEN	Reveal
Dashboard	Client ID
Submission History	**********
わ User Management	******
«	Generate New

Figure 6: API Management Details



#### 5.3 Update credentials.xml

Update the credentials.xml file located on C:\ESGNG with the Client Id and Secret information obtained in the previous subsection.

```
<?xml version="1.0" encoding="utf-8"?>
<credentials>
<clientID<mark>>XX-XXXXXXXXXXXXXXXXXXXXXX</mark></clientID>
<clientSecret>
</credentials>
```

Figure 7. Update ClientID and Client Secret in credentials.xml

#### 5.4 Update the XML File Path

Open the **get\_user\_details.ps1**, **api\_upload.ps1**, **get\_submission\_status.ps1** scripts in PowerShell and update the correct path for the credentials.xml file.

Note: If the file path is not set properly, it will typically result in an error or an exception being raised, depending on the context in which the XML file is being assessed or used.

```
imapi_upload.ps1-Notepad
File Edit Format View Help
[parameter(mandatory=$true)][string]$companyid,
[parameter(mandatory=$true)][string]$filepath,
[parameter(mandatory=$true)][string]$fda_center,
[parameter(mandatory=$true)][string]$Submissiontype
)
function Get-NewToken {
    # Define the API endpoint URL
    $endpoint = "https://external-api-esgng-uat.preprod.fda.gov/as/token.oauth2
    # Define the client ID and client secret
    $xmlFile = "C:\ESGNG\credentials.xml"
```

Figure 8. Update File Path for credentials.xml in Script



#### 5.5 Execute the File Upload Script

- a) Go to the Windows search bar and type **PowerShell**.
- b) Navigate to the folder where the script is located.

#### cd c:\ESGNG

c) Run the **pwsh** command to check PowerShell installation.

C:\ESGNG pwsh <enter>

PowerShell 7.4.0

PS C:\ESGNG>

#### 5.6 Executing API File Upload Script

a) Run the PowerShell script to obtain the userid and companyid, two required file submission parameters. You will receive the response in an email.

PS C:\ESGNG > .\get\_user\_details.ps1 -user\_email "xyz@gmail.com" <enter>

```
C:\WINDOWS\system32\cmd.exe - pwsh
PS C:\ESGNG\ESGNG> .\get_user_details.ps1 -user_email "esg.submitter.1@fda.hhs.gov"
Get User Details
Response : {
    "user_id": 4,
    "user_email": "esg.submitter.1@fda.hhs.gov",
    "company_id": 1017,
    "company_name": "MR Test",
    "company_status": "Approved",
    "authorizing_companies": [
    {
        " authorizing_company_id": 1018,
        "authorizing_company_name": "Shell Test"
    }
],
    "esgngcode": "ESGNG390",
    "esgngdescription": "Company Information retrieved successfully from ESGNG."
}
```

#### Figure 9. Response to Get User Details

If you wish to upload multiple files, combine all the files into a zip archive and then upload the zip file.



- b) In addition to the file path, the upload script requires additional parameters including FDA\_Center and Submission Type for API upload. for down Appendix 2. FDA\_Center and Submission Types for details about both of those parameters.
- c) Run the PowerShell script to API upload. The script executes to create temp credentials for submission, initialize the submission, initialize the file upload, upload the file and finalize the file upload.





C:\WINDOWS\system32\cmd.exe - pwsh PS C:\ESGNG\ESGNG> .\api upload.ps1 cmdlet api upload.ps1 at command pipeline position 1 Supply values for the following parameters: userid: 4 companyid: 1017 filepath: c:\esgng\testfiles\test.doc fda\_center: cber Submissiontype: 510k Initialize submission and retrieve CoreID... VERBOSE: Requested HTTP/1.1 POST with 223-byte payload VERBOSE: Received HTTP/1.1 260-byte response of content type application/json VERBOSE: Content encoding: utf-8 core\_id : MRTest\_2024051027136 cemp\_user : 4-MPTort : 4-MRTest\_2024051027136 temp\_password : 08bedd26-fb57-42a9-bb9f-4d9648cc1520 esgngcode : ESGNG210 esgngdescription : Core Id and Temporary Credentials generated and stored successfully. Initialize file upload... 05-10-2024 16:31:27 VERBOSE: Requested HTTP/1.1 GET with 0-byte payload VERBOSE: Received HTTP/1.1 response of content type application/json of unknown size VERBOSE: Content encoding: utf-8 Actually upload the file... VERBOSE: Requested HTTP/1.1 POST with 1000215-byte payload VERBOSE: Received HTTP/1.1 65-byte response of content type application/json VERBOSE: Content encoding: utf-8 status : DRAFT nessage : Draft saved successfully. : 0 lours : 0 : 0 

 Seconds
 : 0

 Yilliseconds
 : 850

 Ticks
 : 8508452

 TotalDays
 : 9.84774537037037E-06

 TotalHours
 : 0.0002363458888888889

 TotalMinutes : 0.0141807533333333 TotalSeconds : 0.8508452 otalMilliseconds : 850.8452 Finalize file upload... VERBOSE: Requested HTTP/1.1 POST with 189-byte payload VERBOSE: Received HTTP/1.1 33-byte response of content type application/json VERBOSE: Content encoding: utf-8 essage : Successful PS C:\ESGNG\ESGNG>

Figure 10. Output Response to File Upload



# *d*) Once the file upload is completed successfully, you will receive an Acknowledgement email (ACK 1).



#### Figure 61. Acknowledgement 1 email: File Upload Received

e) Once the file is submitted to a center, you will receive another Acknowledgement (ACK 2) email message confirming it was routed to the center.







#### 5.7 Check File Submission Status

Users can check the status of their submission request using the get\_submission\_status PowerShell script and the core\_id for their request.

- 2. Obtain the core\_id from Figure 8. <u>Output Response to File Upload</u> in the previous section.
- 3. Execute below PowerShell script.

PS C:\ESGNG> .\get\_submission\_status.1

cmdlet get\_submission\_status.ps1 at command pipeline position 1

Supply values for the following parameters:

core id: MRTest 2024041030357

#### Get Submission Status

Response: {

"core\_id": "MRTest\_2024041030357",

"status": "Submitted to Center",

"submission\_protocol": "API",

"esgngcode": "ESGNG270",

"esgngdescription": "Submission status retrieved successfully."



# Appendix 1. Common Troubleshooting Issues

During the UAT, if you encounter a common issue described below, follow the recommended troubleshooting steps that may resolve it. You can also always reach out to the ESG NextGen Support Team for assistance by sending an email to <a href="mailto:esgngSupport@fda.hhs.gov">esgngSupport@fda.hhs.gov</a>.

#### **1.1 Versioning Mismatch**

The issue shown in Figure 11 is a script that is not compatible with the version of PowerShell being used (i.e., 7.4.X).



Figure 83. Error on PowerShell scripts with Versioning Mismatch

- a) To check your PowerShell version:
  - i) Open PowerShell .
  - ii) Type \$PSVersionTable.PSVersion and press Enter
  - iii) If the version of PowerShell is not greater than 7.4.X, visit the official <u>PowerShell GitHub releases page</u> or the <u>Microsoft PowerShell website</u> to download and install the latest version.



#### **1.2 Multiple Versions of PowerShell**

The scripts will be executed only from the Windows PowerShell screen. The issue shown in Figure 14 is that there are two versions of PowerShell on the computer.

🔀 Windows PowerShell	2 Windows PowerShell (x86)
Windows PowerShell Copyright (C) Microsoft Corporation. All rights reserved.	Windows PowerShell Copyright (C) Microsoft Corporation. All rights reserved.
Try the new cross-platform PowerShell https://aka.ms/pscore6	Try the new cross-platform PowerShell https://aka.ms/pscore6
PS C:\Users\Barun.Poudel> pwsh PowerShell 7.4.2 PS C:\Users\Barun.Poudel> \$PSVersionTable.PSVersion Major Minor Patch PreReleaseLabel BuildLabel	PS C:\Users\Barun.Poudel> \$PSVersionTable.PSVersion Major Minor Build Revision  5 1 19041 4291
7 4 2 PS C:\Users\Barun.Poudel>	PS C:\Users\Barun.Poudel>

Figure 94. Different PowerShell Versions on the Same Machine

To resolve this issue:

- a) Delete the older version of PowerShell.
- b) If the remaining version of PowerShell is not greater than 7.4.X, visit the official <u>PowerShell GitHub releases page</u> or the <u>Microsoft PowerShell</u> <u>website</u> to download and install the latest version.

If you have trouble installing modules due to version mismatches, try using the **- RequiredVersion** parameter when installing the module to specify a compatible version.

• You can also use the **Install-Module -Scope CurrentUser** command if you encounter permission issues with installing modules systemwide.

#### **1.3 PowerShell Execution Policy**

If you encounter an issue after copying the files to the desired location, it may be because PowerShell's execution policy restricts the running of scripts for security reasons.



Figure 15. Execution Policy Error



To resolve this issue:

Navigate to the folder where the file is located and execute the following command.

PS C:\ESGNG> Set-ExecutionPolic	y -ExecutionPolicy	Unrestricted -
Scope CurrentUser		

If the above command does not fix the issue, execute the following commands from the folder where the files are located.

- a. Unblock-File get\_submission\_status.ps1
- b. Unblock-File api\_upload.ps1
- c. Unblock-File get\_user\_details.ps1
- d. Unblock-File api\_upload.ps1



# Appendix 2. FDA\_Center and Submission Types

FDA_Center	Submission Type	Additional Info
CBER	510K	
CBER	AERS	
CBER	AERS ATTACHMENTS	
CBER	AERS_ATTACHMENTS_PREMKT_CBER	
CBER	AERS_PREMKT_CBER	
CBER	BEST	
CBER	CDISC	
CBER	EBLA	
CBER	eDMF	
CBER	EIDE	
CBER	EIND	
CBER	EUA	
CBER	H1N1_Lot_Release	
CBER	Lot_Release_Protocol	
CBER	NDA	
CBER	РМА	
CBER	Pre_IND	
CBER	Promotional_Materials	
CBER	QSUBS	
CBER	SEND_PILOT	Test Only
CBER	SPL_LDD	
CBER	VAERS	
CDER	ACA6004_Drug_Samples	
CDER	AERS	
CDER	AERS Attachment IND	Test Only
CDER	AERS ATTACHMENTS	
CDER	AERS IND	Test Only
CDER	AERS_Attachments_PREMKT	Test Only
CDER	AERS_Attachments_PREMKT_CDER	
CDER	AERS_PREMKT	Test Only
CDER	AERS_PREMKT_CDER	
CDER	ECTD	
CDER	ECTD WAIVED	
CDER	EDMF TYPEIII	



CDER	EIND	
CDER	PFC	
CDER	FFU-PILOT	
CDER	GDUFA_Facility_Registration	
CDER	PFC	
CDER	POR Large Molecule Documents	
CDER	Voluntary_Direct_Aes	
CDRH	Adverse Events	
CDRH	Electronic_Submissions	
CDRH	GUDID	
СТР	Adverse_Events	
СТР	Electronic_Submissions	
СVМ	Adverse_Events_Reports	
СVМ	eSubmitter	
СVМ	Electronic_Submissions	
CVM_VDD	eSubmitter	Test Only
HealthCanada	Transaction	
HFP	DSR_Adverse_Events	
HFP	EON-Payload-Files	
HFC	Food_Pilot_Listing	
HFC	Form3479	
HFC	Form3480	
HFC	Form3480A	
HFC	Form3503	
HFC	Form3665	
HFC	From3666	
HFC	Form3667	
HFC	NDI	
HFC	Threshold_of_Regulation	
MWP	MWP_Report	Test Only
ос	OCAC	
ос	SPL	
OOPD	HUD_Designation_Requests	Test Only
OOPD	Orphan_drug_Designation_Requests	Test Only
ORA	Document_requests	
ORA	POR Small Molecule Documents	
OPQ	704a4 Pharma Inspection Records	



# **Appendix 3. API Specifications**

#### **API** Name: OAuth2 Token Endpoint

Base URL: https://external-api-esgng-uat.preprod.fda.gov
Endpoint: /as/token.oauth2
HTTP Method: POST

#### **Description:**

This API provides an access token for client authentication using the OAuth2 client\_credentials grant type. The token allows the client to authenticate and interact with other secured endpoints on the server.

#### Authentication:

- Grant Type: client\_credentials
- Scope: openid profile

#### **Request Details:**

• URL:

```
https://external-api-esgng-
uat.preprod.fda.gov/as/token.oauth2?grant_type=client_credentials&scop
e=openid%20profile
```

- Method: POST
- Headers:
  - o Content-Type:application/x-www-form-URLencoded
- Body (form-data):

```
client_id=your_client_id
client_secret=your_client_secret
```



#### **Request Example:**

```
curl --location 'https://external-api-esgng-
uat.preprod.fda.gov/as/token.oauth2?grant_type=client_credentials&scope=openid%20pro
file' \
--header 'Content-Type: application/x-www-form-urlencoded' \
--data-urlencode 'client_id= your_client_id' \
--data-urlencode 'client_secret= your client secret'
```

#### **Response Details:**

#### **Successful Response:**

- Status Code: 200 OK
- Response Body (JSON):

#### **Response Output**

```
{
    "access_token": "eyJhbGciOiJSUzI1NiIsIn...",
    "token_type": "Bearer",
    "expires_in": 3600,
}
```

#### **Error Responses:**

- Status Code: 400 Bad Request
  - **Response Body (JSON):**

#### **Response Output**

```
HTTP POST on resource 'https://ssoext.preprod.fda.gov/as/token.oauth2' failed: bad request (400).
```

- Status Code: 401 Unauthorized
  - **Response Body (JSON):**

#### **Response Output**

#### {





• Status Code: 500 Internal Server Error



#### **Parameters:**

#### **Query Parameters:**

- grant\_type:
  - **Description**: The OAuth 2.0 grant type. In this case, it's client\_credentials.
  - o **Type:** string
  - **Required**: Yes
  - o **Example:** client\_credentials
- scope:
  - **Description**: Requested scopes of the access token. Here, the scopes are openid and profile.
  - o Type: string
  - **Required**: Yes
  - o **Example:** openid profile

#### **Body Parameters (x-www-form-urlencoded):**

- client\_id:
  - **Description**: The client ID provided by the authorization server.
  - o **Type:** string
  - **Required**: Yes
  - **Example:** your\_client\_id
- client\_secret:
  - **Description**: The client secret corresponding to the client ID.
  - o **Type:** string
  - Required: Yes



o Example: your\_client\_secret

#### **Response Codes:**

- 200 OK: The access token was successfully generated.
- 400 Bad Request: Invalid request, possibly due to missing parameters.
- 401 Unauthorized: Authentication failure, incorrect client ID or secret.
- 500 Internal Server Error: Unexpected server error.



#### API Name: ESGNG Credential Submission API PROD Submission

Base URL: https://external-api-esgng-uat.preprod.fda.gov Endpoint: /api/esgng/v1/credentials/api HTTP Method: POST

#### **Description:**

This API allows clients to submit credentials for a user to the FDA's ESGNG (Electronic Submissions Gateway Next Generation) system. The request requires an access token for authentication and includes various details about the submission.

#### Authentication:

- **Type:** Bearer Token (OAuth 2.0)
- Token: The access\_token obtained from the OAuth token endpoint.

#### **Request Details:**

- URL: https://external-api-esgnguat.preprod.fda.gov/api/esgng/v1/credentials/api
- Method: POST
- Headers:
  - o Authorization:Bearer {access\_token}
  - o Content-Type:application/json
- Body (JSON):

```
{
  "user_id": "4505",
  "fda_center": "CBER",
  "company_id": "5842",
  "submission_type": "510K",
  "submission_name": "Test from Postman",
  "submission_protocol": "API",
  "file_count": 1,
```



```
"description": "this is submission version description."
```

#### **Request Example:**

}

```
curl --location 'https://external-api-esgng-
uat.preprod.fda.gov/api/esgng/v1/credentials/api' \
--header 'accesstoken: eyJhbGciOiJIUzI1NiIsInR5cCI6IkpXVCJ9...' \
--header 'Content-Type: application/json' \
--data '{
    "user_id": "4909",
    "fda_center": "CBER",
    "company_id": "5842",
    "submission_type": "510K",
    "submission_name": "Testing from Postman",
    "submission_protocol": "API",
    "file_count": 1,
    "description": "Testing from Postman"
}'
```

#### **Response Details:**

#### **Successful Response:**

- Status Code: 200 OK
- Response Body (JSON):

#### **Response Output**

#### {

```
"core id": "ci240911125314.86907a8a03df4427875feb2140a50bcc",
```

"temp user": "4909-ci240911125314.86907a8a03df4427875feb2140a50bcc",

```
"temp password": "eddbefca-a3d7-4b5a-805b-de0e68dd48ea",
```

```
"esgngcode": "ESGNG210",
```

"esgngdescription": "Core Id and Temporary Credentials generated and stored successfully."

}



#### **Error Responses:**

• Status Code: 400 Bad Request • Response Body (JSON):

Response Output
{
 "esgngcode": "ESGNG219",
 "esgngdescription": "Invalid user, company, or center submission type. Please
check request inputs and try again.",
 "message": "Bad request"
}

- Status Code: 400 Invalid token
  - Response Body (JSON):

Response Output
{
"detailedDescription": "HTTP POST on resource 'http://ESGSta-MyNLB-
L3p10ZLfCKpB-98584b6b2ed83b12.elb.us-gov-west-1.amazonaws.com/as/validate' failed:
internal server error (500).",
"error": "Invalid Grant or Invalid Credentials"
}

• Status Code: 500 Internal Server Error • Response Body:





#### **Parameters:**

#### **Header Parameters:**

- Authorization:
  - **Description**: The Bearer token obtained via the OAuth 2.0 token endpoint.
  - o **Type**: string
  - **Required**: Yes
  - **Example**: Bearer eyJhbGciOiJIUzI1NiIsInR5cCI6IkpXVCJ9...

#### **Body Parameters (JSON):**

- user\_id:
  - **Description**: The ID of the user making the submission which can be obtained by GetCompanyInfo API call
  - o **Type**: string
  - **Required**: Yes
  - **Example:** "4505"
- fda\_center:
  - **Description**: The FDA center associated with the submission (e.g., CBER, CDER, etc.).
  - o **Type:** string
  - Required: Yes
  - Example: "CBER"
- company\_id:
  - **Description**: The company ID associated with the submission which can be retrieved by GetCompanyInfo API call
  - o Type: string
  - **Required**: Yes
  - o **Example:** "5842"
- submission\_type:
  - **Description**: The type of submission being made (e.g., 510K, NDA).
  - o **Type**: string
  - **Required**: Yes
  - **Example**: "510K"
- submission\_name:
  - **Description**: The name of the submission.
  - o **Type**: string
  - Required: Yes
  - o Example: "Test from Postman"
- submission\_protocol:



- **Description**: The protocol used for the submission (e.g., API).
- o **Type**: string
- **Required**: Yes
- **Example**: "API"
- file\_count:
  - **Description**: The number of files included in the submission
  - o **Type**: integer
  - **Required**: Yes
  - **Example**: 1
- description:
  - **Description**: A description of the submission or submission version.
  - o **Type**: string
  - **Required**: Yes
  - o **Example**: "Submission details"

**Response Codes:** 

- 200 OK: The submission was successful, and a submission ID is returned.
- 400 Bad Request: Invalid input or missing required parameters.
- 401 Unauthorized: Invalid or expired access token.
- **500 Internal Server Error**: Unexpected server-side error.



#### **API Name: ESGNG Credential Submission API Test Submission**

Base URL: https://external-api-esgng-uat.preprod.fda.gov Endpoint: /api/esgng/v1/credentials/api/test HTTP Method: POST

#### **Description:**

This API allows clients to submit credentials for a user to the FDA's ESGNG (Electronic Submissions Gateway Next Generation) system. The request requires an access token for authentication and includes various details about the submission.

#### Authentication:

- **Type:** Bearer Token (OAuth 2.0)
- Token: The access\_token obtained from the OAuth token endpoint.

#### **Request Details:**

- URL: https://external-api-esgnguat.preprod.fda.gov/api/esgng/v1/credentials/api/test
- Method: POST
- Headers:
  - o Authorization:Bearer {access\_token}
  - o Content-Type:application/json
- Body (JSON):

```
{
    "user_id": "4505",
    "fda_center": "CBER",
    "company_id": "5842",
    "submission_type": "510K",
    "submission_name": "Test from Postman",
    "submission_protocol": "API",
    "file_count": 1,
```



```
"description": "this is submission version description."
```

#### **Request Example:**

}

```
curl --location 'https://external-api-esgng-
uat.preprod.fda.gov/api/esgng/v1/credentials/api/test' \
--header 'accesstoken: eyJhbGciOiJIUzI1NiIsInR5cCI6IkpXVCJ9...' \
--header 'Content-Type: application/json' \
--data '{
    "user_id": "4909",
    "fda_center": "CBER",
    "company_id": "5842",
    "submission_type": "510K",
    "submission_name": "Testing from Postman",
    "submission_protocol": "API",
    "file_count": 1,
    "description": "Testing from Postman"
}'
```

#### **Response Details:**

#### **Successful Response:**

- Status Code: 200 OK
- Response Body (JSON):

#### **Response Output**

#### {

```
"core id": "ci240911125314.86907a8a03df4427875feb2140a50bcc",
```

"temp\_user": "4909-ci240911125314.86907a8a03df4427875feb2140a50bcc",

```
"temp password": "eddbefca-a3d7-4b5a-805b-de0e68dd48ea",
```

```
"esgngcode": "ESGNG210",
```

"esgngdescription": "Core Id and Temporary Credentials generated and stored successfully."

}



#### **Error Responses:**

• Status Code: 400 Bad Request • Response Body (JSON):

Response Output
{
 "esgngcode": "ESGNG219",
 "esgngdescription": "Invalid user, company, or center submission type. Please
check request inputs and try again.",
 "message": "Bad request"
}

- Status Code: 400 Invalid token
  - Response Body (JSON):

Response Output
{
"detailedDescription": "HTTP POST on resource 'http://ESGSta-MyNLB-
L3p10ZLfCKpB-98584b6b2ed83b12.elb.us-gov-west-1.amazonaws.com/as/validate' failed:
internal server error (500).",
"error": "Invalid Grant or Invalid Credentials"
}

• Status Code: 500 Internal Server Error • Response Body:





#### **Parameters:**

#### **Header Parameters:**

- Authorization:
  - **Description**: The Bearer token obtained via the OAuth 2.0 token endpoint.
  - o **Type**: string
  - **Required**: Yes
  - **Example**: Bearer eyJhbGciOiJIUzI1NiIsInR5cCI6IkpXVCJ9...

#### **Body Parameters (JSON):**

- user\_id:
  - **Description**: The ID of the user making the submission which can be obtained by GetCompanyInfo API call
  - o **Type**: string
  - **Required**: Yes
  - **Example:** "4505"
- fda\_center:
  - **Description**: The FDA center associated with the submission (e.g., CBER, CDER, etc.).
  - o **Type:** string
  - Required: Yes
  - Example: "CBER"
- company\_id:
  - **Description**: The company ID associated with the submission which can be retrieved by GetCompanyInfo API call
  - o Type: string
  - **Required**: Yes
  - o **Example:** "5842"
- submission\_type:
  - **Description**: The type of submission being made (e.g., 510K, NDA).
  - o **Type**: string
  - **Required**: Yes
  - **Example**: "510K"
- submission\_name:
  - **Description**: The name of the submission.
  - o **Type**: string
  - Required: Yes
  - o Example: "Test from Postman"
- submission\_protocol:



- **Description**: The protocol used for the submission (e.g., API).
- o **Type**: string
- **Required**: Yes
- **Example**: "API"
- file\_count:
  - **Description**: The number of files included in the submission
  - o **Type**: integer
  - **Required**: Yes
  - Example: 1
- description:
  - **Description**: A description of the submission or submission version.
  - o **Type**: string
  - **Required**: Yes
  - o **Example**: "Submission details"

#### **Response Codes:**

- 200 OK: The submission was successful, and a submission ID is returned.
- 400 Bad Request: Invalid input or missing required parameters.
- 401 Unauthorized: Invalid or expired access token.
- **500 Internal Server Error**: Unexpected server-side error.



#### API Name: ESGNG File Payload (No Token Required)

Base URL: https://upload-api-esgng.uat.preprod.fda.gov Endpoint: /rest/forms/v1/fileupload/payload HTTP Method: GET

#### **Description:**

This API allows clients to retrieve file Payload ID or metadata without authentication via an access token. No input parameters are required for this request.

#### Authentication:

• **Type:** No authentication required for this request.

#### **Request Details:**

- URL: https://upload-api-esgnguat.preprod.fda.gov/rest/forms/v1/fileupload/payload
- Method: GET
- Headers:
  - No authentication headers are required.
  - o Content-Type:application/json

#### **Request Example:**

curl --location 'https://upload-api-esgnguat.preprod.fda.gov/rest/forms/v1/fileupload/payload'

#### **Response Details:**

**Successful Response:** 

- Status Code: 200 OK
- Response Body (JSON):



Response Output
f and the second s
"data": {
"payloadId": "6f10c466-b10a-43be-84d2-fc27cc661a28",
"uploadFileLink": "https://upload-api-esgng- uat.preprod.fda.gov/rest/forms/v1/fileupload/payload/6f10c466-b10a-43be-84d2- fc27cc661a28/file",
"submitFormLink": "https://upload-api-esgng- uat.preprod.fda.gov/rest/forms/v1/fileupload/payload/6f10c466-b10a-43be-84d2- fc27cc661a28/submit"
}
}

#### **Error Responses:**

• Status Code: 500 Internal Server Error • Response Body:

Response Output	
"error": {	
"code": 500,	
"message": "Internal server error. Please contact the server administrator.",	
"status": "INTERNAL_ERROR"	
}	
}	



#### **Parameters:**

• No input parameters are required for this request.

#### **Response Codes:**

- 200 OK: File information successfully retrieved.
- 500 Internal Server Error: Unexpected server-side error.



#### API Name: ESGNG File Upload API with Payload ID

```
Base URL: https://upload-api-esgng-uat.preprod.fda.gov
Endpoint: /rest/forms/v1/fileupload/payload/{payloadID}/file
HTTP Method: POST
```

#### **Description:**

This API allows clients to upload a file to the FDA's ESGNG system by sending a multipart/form-data request. The file is uploaded to a specific payloadID that is obtained from a previous request.

#### Authentication:

- **Type:** Bearer Token (OAuth 2.0)
- **Token:** The access\_token obtained from the OAuth token endpoint.

#### **Request Details:**

- URL:https://upload-api-esgnguat.preprod.fda.gov/rest/forms/v1/fileupload/payload/{payloadID}/file
  - o Example: https://upload-api-esgnguat.preprod.fda.gov/rest/forms/v1/fileupload/payload/5b5f4212-2fc1-4f63-b0e9-3ce62876dc00/file
- Method: POST
- Body (multipart/form-data):
  - **file**: The binary file to be uploaded, specified by its file path.

#### **Request Example:**

```
curl --location 'https://upload-api-esgng-
uat.preprod.fda.gov/rest/forms/v1/fileupload/payload/4c2bd633-160e-4374-bd32-
0f48d02b5132/file' \
--form 'file=@"/path/to/your/file.zip"'
```



#### **Response Details:**

Successful Response:

- Status Code: 200 OK
- Response Body (JSON):

Res	Response Output				
{					
	"data"	: {			
	"s	tatus": "DRAFT",			
	"m	essage": "Draft saved successfully."			
	}				
}					

#### **Error Responses:**

• Status Code: 400 Bad Request • Response Body (JSON):

Respon	se Output
{	
"er	ror": {
	"code": 400,
'1'.",	"message": "Total number of upload files should be less than or equal to
	"status": "INVALID_FILE_COUNT"
}	
}	

- Status Code: 500 Internal Server Error
  - **Response Body:**



Response Output
{
"error": {
"code": 500,
"message": "Internal server error. Please contact the server administrator.",
"status": "INTERNAL_ERROR"
}
}

#### **Parameters:**

#### **URL Path Parameter:**

- payloadID:
  - **Description**: The unique identifier for the payload from the previous request.
  - Type: string
  - **Required**: Yes
  - **Example:** 5b5f4212-2fc1-4f63-b0e9-3ce62876dc00

#### **Header Parameters:**

- Authorization:
  - **Description**: The Bearer token obtained via the OAuth 2.0 token endpoint.
  - o **Type:** string
  - **Required**: Yes
  - **Example**: Bearer eyJhbGciOiJIUzI1NiIsInR5cCI6IkpXVCJ9...

#### **Body Parameters (multipart/form-data):**

- file:
  - **Description**: The file to be uploaded.
  - o **Type**: binary



• **Required**: Yes

o Example:/path/to/your/file.zip

#### **Response Codes:**

- 200 OK: File uploaded successfully, returns the file ID and payload ID.
- 400 Bad Request: Invalid file format or missing fields.
- 500 Internal Server Error: Unexpected server-side error.



#### **API Name: ESGNG File Submit API**

```
Base URL: https://upload-api-esgng-uat.preprod.fda.gov
Endpoint: /rest/forms/v1/fileupload/payload/{payloadID}/submit
HTTP Method: POST
```

#### **Description:**

This API allows clients to submit a payload by providing the username, temp\_password, and sha256\_checksum in the request body. No access token is required for this request.

#### Authentication:

• Type: No access token required for this request.

#### **Request Details:**

• URL:

```
https://upload-api-esgng-
uat.preprod.fda.gov/rest/forms/v1/fileupload/payload/{payloadID}/submi
t
```

• Example:

```
https://upload-api-
esgng.uat.preprod.fda.gov/rest/forms/v1/fileupload/payload/19019
65f-f2a4-4e47-84a4-f6db16c07d00/submit
```

- Method: POST
- Headers:
  - o Content-Type:application/json
- Body (raw JSON):
  - o username: The temp username associated with the request.
  - o password: A temporary password for authentication.
  - sha256\_checksum: The SHA-256 checksum of the payload to ensure data integrity.

#### **Request Example:**



```
curl --location 'https://upload-api-esgng-
uat.preprod.fda.gov/rest/forms/v1/fileupload/payload/4c2bd633-160e-4374-bd32-
0f48d02b5132/submit' \
--header 'Content-Type: application/json' \
--data '{
    "username": "4909-ci240918122153.ec1012163cc944c2913d132e42ecd02a",
    "password": "293dc314-219a-476a-a86e-6a64f174dfda",
    "sha256_checksum":
"B6630F7D0FF76F53F21B472F0D383B41A0B8A730A29282F12DB435DC390DFDEB"
}'
```

#### **Response Details:**

#### **Successful Response:**

- Status Code: 200 OK
- Response Body (JSON):

Response Output
Response Output
{
"data": {
"message": "Successful"
}
}

#### **Error Responses:**

Status Code: 400 Bad Request
 Response Body (JSON):

Response Output		
{		



	"data": {						
	"message": "Successful"						
	}						
}							

- Status Code: 500 Internal Server Error
  - **Response Body:**

Response Output
{
"error": {
"code": 500,
"message": "Internal server error. Please contact the server administrator.",
"status": "INTERNAL_ERROR"
}
}

#### **Parameters:**

**URL Path Parameter:** 

- payloadID:
  - **Description**: The unique identifier for the payload to be submitted.
  - o Type: string
  - **Required**: Yes
  - o **Example:** 1901965f-f2a4-4e47-84a4-f6db16c07d00

#### **Body Parameters (raw JSON):**

- username:
  - **Description**: The unique username associated with the request.



- o **Type:** string
- **Required**: Yes
- o **Example**: "4847-ci240812190348.7beb65f0e2f747f5beb21effa03c34ab"
- password:
  - **Description**: A temporary password provided for authentication.
  - o **Type**: string
  - **Required**: Yes
  - o **Example**: "3420c46f-872f-4d4a-95f8-ed8639e1b653"
- sha256\_checksum:
  - **Description**: The SHA-256 checksum of the file to verify integrity.
  - o **Type:** string
  - **Required**: Yes
  - Example:

```
"d29751f2649b32ff572b5e0a9f541ea660a50f94ff0beedfb0b692b924cc802
5"
```

#### **Response Codes:**

- 200 OK: Payload successfully submitted, returns submission ID and payload ID.
- 500 Internal Server Error: Unexpected server-side error.



#### API Name: ESGNG Get Submission Status API

Base URL: https://external-api-esgng-uat.preprod.fda.gov/api/esgng/v1
Endpoint: /submissions/{core\_id}
HTTP Method: GET

#### **Description:**

This API retrieves the status of a specific submission in the ESGNG system by passing a core\_id as a query parameter. The core\_id is a unique identifier for the submission.

#### Authentication:

- **Type:** Bearer Token (OAuth 2.0)
- Token: The access token obtained from the OAuth token endpoint.

#### **Request Details:**

#### • URL:

```
https://external-api-esgng-
uat.preprod.fda.gov/api/esgng/v1/submissions/core id}
```

• Example:

```
https://external-api-esgng-
uat.preprod.fda.gov/api/esgng/v1/submissions/ci240911153205.2ce7
7ba34c8b4d668005518f2826386c
```

- Method: GET
- Headers:
  - o Authorization:Bearer {access\_token}
  - o Content-Type:application/json

#### **Request Example:**



curl --location --request GET 'https://external-api-esgnguat.preprod.fda.gov/api/esgng/v1/submissions/ci240911153205.2ce77ba34c8b4d66 8005518f2826386c' \ --header 'Authorization: Bearer eyJhbGciOiJIUzI1NiIsInR5cCI6IkpXVCJ9...' \ --header 'Content-Type: application/json'

#### **Query Parameters:**

- core\_id:
  - **Description**: The unique core ID for the submission you want to check the status of.
  - o **Type:** string
  - **Required**: Yes
  - o **Example:** ci240911153205.2ce77ba34c8b4d668005518f2826386c

#### **Response Details:**

Successful Response:

- Status Code: 200 OK
- Response Body (JSON):

Res	Response Output				
{					
	"core_id": "ci240911153205.2ce77ba34c8b4d668005518f2826386c",				
	"status": "Submitted to Center",				
	"submission_protocol": "USP",				
	"esgngcode": "ESGNG270",				
	"esgngdescription": "Submission status retrieved successfully."				
}					

#### **Error Responses:**



- Status Code: 400 Bad Request
  - **Response Body (JSON):**

#### **Response Output**

#### "esgngcode": "ESGNG271",

"esgngdescription": "Invalid Request. Please check request inputs and try again.",

"message": "Bad request"

}

- Status Code: Fail Response
  - Response Body (JSON):

Response Output
"detailedDescription": "HTTP POST on resource 'http://ESGSta-MyNLB-
L3p10ZLfCKpB-98584b6b2ed83b12.elb.us-gov-west-1.amazonaws.com/as/validate' failed:
internal server error (500).",
"error": null
}

- Status Code: 500 Internal Server Error
  - **Response Body:**







#### **Response Codes:**

- 200 OK: Submission status retrieved successfully.
- 400 Bad Request: The core ID is invalid or missing.
- 400 Unauthorized: Invalid or expired access token.
- 500 Internal Server Error: Unexpected server-side error.



#### API Name: ESGNG Get Companies by User Email API

Base URL: https://external-api-esgng-uat.preprod.fda.gov
Endpoint: /api/esgng/v1/companies
HTTP Method: GET

#### **Description:**

This API retrieves the list of companies associated with a specific user by passing the user's email address as a query parameter. The response provides details about the companies linked to the user.

#### Authentication:

- **Type:** Bearer Token (OAuth 2.0)
- Token: The access token obtained from the OAuth token endpoint.

#### **Request Details:**

- URL: https://external-apiesgng.uat.preprod.fda.gov/api/esgng/v1/companies?user\_email={user\_emai
  - 1}
    - o Example: https://external-api-esgnguat.preprod.fda.gov/api/esgng/v1/companies?user\_email=esg.submit ter.1@fda.hhs.gov
- Method: GET
- Headers:
  - o Authorization:Bearer {access token}
  - o Content-Type:application/json

#### **Request Example:**

```
curl --location 'https://external-api-esgng-
uat.preprod.fda.gov/api/esgng/v1/submissions/ci240918122153.ec1012163cc944c2913d132e
42ecd02a' \
--header 'accesstoken: eyJhbGciOiJIUzI1NiIsInR5cCI6IkpXVCJ9...'
```

#### **Query Parameters:**



- user\_email:
  - **Description**: The email address of the user whose associated companies need to be retrieved.
  - o **Type:** string
  - **Required**: Yes
  - o **Example**: esgngtest1@gmail.com

#### **Response Details:**

Successful Response:

- Status Code: 200 OK
- Response Body (JSON):

#### **Response Output**

```
{
    "user_id": 4909,
    "user_email": "esgngtestl@gmail.com",
    "company_id": 5842,
    "company_name": "Auth Shell myrtle",
    "company_status": "Approved",
    "esgngcode": "ESGNG390",
    "esgngdescription": "Company Information retrieved successfully from ESGNG."
}
```



#### **Error Responses:**

• Status Code: 400 Bad Request • Response Body (JSON):



- Status Code: 400 Fail Response
  - Response Body (JSON):

#### **Response Output**

# { "detailedDescription": "HTTP POST on resource 'http://ESGSta-MyNLBL3p10ZLfCKpB-98584b6b2ed83b12.elb.us-gov-west-1.amazonaws.com/as/validate' failed: internal server error (500).",

"error": "Invalid Grant or Invalid Credentials"

}



• Status Code: 500 Internal Server Error • Response Body:

Response Output
{
"error": {
"code": 500,
"message": "Internal server error. Please contact the server administrator.",
"status": "INTERNAL_ERROR"
}
}

#### **Response Codes:**

- **200 OK**: Companies associated with the user were retrieved successfully.
- 400 Bad Request: The email parameter is invalid or missing.
- 400 Fail Response: Invalid or expired access token.
- 500 Internal Server Error: Unexpected server-side error.



#### **API Name: ESGNG Get Acknowledgement API**

Base URL: https://external-api-esgng-uat.preprod.fda.gov Endpoint: /api/esgng/v1/acknowledgements/{acknowledgement\_id} HTTP Method: GET

#### **Description:**

This API retrieves the details of a specific acknowledgment based on the acknowledgment ID provided in the URL path.

#### Authentication:

- **Type:** Bearer Token (OAuth 2.0)
- Token: The access token obtained from the OAuth token endpoint.

#### **Request Details:**

- URL: https://external-api-esgnguat.preprod.fda.gov/api/esgng/v1/acknowledgements/{acknowledgement id}
  - o Example: https://external-apiesgng.uat.preprod.fda.gov/api/esgng/v1/acknowledgements/ci240828 170030.0ce16ba6d3944975977c9594d0fabb74
- Method: GET
- Headers:
  - o Authorization:Bearer {access\_token}
  - o Content-Type:application/json

#### **Request Example:**

```
curl --location --request GET 'https://external-api-esgng-
uat.preprod.fda.gov/api/esgng/v1/acknowledgements/ci240828170030.0ce16ba6d39
44975977c9594d0fabb74' \
```

#### --header 'accesstoken: eyJhbGciOiJIUzI1NiIsInR5cCI6IkpXVCJ9...'

#### **Path Parameters:**



- acknowledgement\_id:
  - **Description**: The unique identifier for the acknowledgment you want to retrieve.
  - o **Type:** string
  - **Required**: Yes
  - o **Example:** ci240828170030.0ce16ba6d3944975977c9594d0fabb74

#### **Response Details:**

Successful Response:

- Status Code: 200 OK
- Response Body (JSON):

#### **Response Output**

```
"core id": "ci240828170030.0ce16ba6d3944975977c9594d0fabb74",
    "acknowledgements": [
            "acknowledgement": "ACK1c",
            "status": "Upload Received",
            "message": "\n\n From: donotreply@fda.hhs.gov\n To:
esgngtestl@gmail.com\n Subject: ESG Submission - ACK1 - Upload Received:
ci240828170030.0ce16ba6d3944975977c9594d0fabb74\n\nSubmission
ci240828170030.0ce16ba6d3944975977c9594d0fabb74 has been successfully received by
ESG.\n\n Company Name: Auth Shell myrtle\n Core ID:
ci240828170030.0ce16ba6d3944975977c9594d0fabb74\n\tFile Type: SINGLE\n\tFile Count
Received: 1\n\tFile Count Identified to be Received: 1\n\tTotal File Size: 2.39
MB\n\tOrigination Date/Time: 08/28/2024 13:00:31 EDT\n\nNext Step: Submission to
be delivered to CTP",
            "created by": "4909",
            "created date": "08-28-2024, 17:06:43"
            "acknowledgement": "ACK2",
            "status": "Submitted to Center",
```



```
"message": "\n\n From: donotreply@fda.hhs.gov\n To:
esgngtestl@gmail.com\n Subject: ESG Submission - ACK2 - Submitted to Center:
ci240828170030.0ce16ba6d3944975977c9594d0fabb74\n\Submission
ci240828170030.0ce16ba6d3944975977c9594d0fabb74 has been successfully submitted to
CTP\n\n Company Name: Auth Shell myrtle\n\n\tCore ID:
ci240828170030.0ce16ba6d3944975977c9594d0fabb74\n\tFile Type: SINGLE\n\tFile Count
Received: 1\n\tFile Count Identified to be Received: 1\n\tTotal File Size: 2.39
MB\n\torigination Date/Time: 08/28/2024 13:00:31 EDT\n\tCenter Receipt Date/Time:
08/28/2024 13:06:43 EDT\n\t\tIf the center received your submission after 4:30 PM
EST, the official receipt date for the submission is the next government business
day.\n\nNext Step: CTP to review submission.",
    "created_by": "4909",
    "created_date": "09-28-2024, 17:06:44"
    }
    ],
    "created_date": "ESGNG360",
    "esgngdescription": "Retrieved all acknowledgements for the given submission."
  }
}
```

#### **Error Responses:**

Status Code: 400 Bad Request
 o Response Body (JSON):

#### **Response Output**

```
{
    "esgngcode": "ESGNG361",
    "esgngdescription": "Invalid Request. Please check request inputs and try
again.",
    "message": "Bad request"
}
```

- Status Code: Fail Response
  - Response Body (JSON):



# Response Output { "detailedDescription": "HTTP POST on resource 'http://ESGSta-MyNLBL3p10ZLfCKpB-98584b6b2ed83b12.elb.us-gov-west-1.amazonaws.com/as/validate' failed: internal server error (500).", "error": null }

- Status Code: 500 Internal Server Error
  - **Response Body:**



#### **Response Codes:**

- 200 OK: Acknowledgment details retrieved successfully.
- 400 Bad Request: The acknowledgment ID is invalid.
- 400 Unauthorized: Invalid token.
- 500 Internal Server Error: Unexpected server-side error.

# **Appendix 4. API Upload Test Cases**



# **Appendix 5. Industry Partner APIs**

No	API Endpoint	API Descriptio n (Industry Partners)	Request Method	Request Input (Sample values)	Request Output (Sample values)
1	https://external- api-esgng- uat.preprod.fda.gov /as/token.oauth2?g rant type=client cr edentials&scope=o penid%20profile	API to generate oAuth Token	POST	Request Body with x-www-form- urlencoded Keys Values: client_secret—Secret generated from API Management client_id ID generated from API Management <u>NOTE:</u> The values are constant which are from ICAM client credentials.	<pre>{     "access_token":     "eyJhbGciOiJSUzI1NiIsImtpZCI6InNzb2tleSIsIng1dCl6In g4U3o5d1I1dmdjOHZZUOluLUM4cHUxRWVVUSIsInBp LmF0bSI6IJyMWMifQ.eyJzY29wZSI6Im9wZW5pZCBwc m9maWxlliwiYXV0aG9yaXphdGlvbl9kZXRhaWxzIjpbXS wiY2xpZW50X2lkIjoiZGNyLW11bGVzb2ZOliwiaXNzIjoia HR0cHM6Ly9zc28uZmRhLmdvdiIsImF1ZCI6IkNUUF9IU 3VibWlzcdcvbl9Nb2RfREVWX0V4dCIsImV4cCl6MTcwO TkyODkzM30.OR4m9O2q8Us3UOGnmQbv5J3vTYVKE_ kLhgvBfBmbco5gAAOtpLQYbkNIHtuZ8e9PHd6IMMtqD yD5i7kIAdUE36z7UncVAp4zaND- xy2XixtOL5Gk0HQpwMMaBvJelWEHtUZoWWCnzvinU s2nu0Rwm0EK86sHIcXAO9KGBtOPsan_f4mhz82yhXGc rCqOlzwdHrXvwLBkRkdj- xpCUAiTJyJ3txdncHL6frNP93QZ431kgGfKLPH3fzyvpF- KOHqTGsTd02pDRmEc3DjsSlbU4pNT7B2Xe9BTOgVX_ Xt37_cHaziRqcb3zwitoUl3VvDAaZl2hNYnbuOikJZEhmy A", "token_type": "Bearer", "expires_in": 3600}</pre>
2	https://external-api- esgng- uat.preprod.fda.gov	Generate submission id and temp credentials	GET	Request Body: { "user_id": "2",	{ "core_id": "CmpAssociatesInc_2023110733023", "temp_user": "1-CmpAssociatesInc_2023110733023",



No	API Endpoint	API Descriptio n (Industry Partners)	Request Method	Request Input (Sample values)	Request Output (Sample values)
	<u>/api/esgng/v1/cred</u> entials/api			"fda_center": "CBER", "company_id": "2", "authorizing_company_id": "2", "submission_type": "510K", "submission_name": "Product Name7", "file_count": 23, "description": "this is submission version description", "submission_protocol": "API" } Note: Please pass accesstoken in a header Key – Values accesstoken - {accesstoken}	"temp_password": "17948854-108c-4831-9000- 0859c52fefc0", "esgngcode": "ESGNG210", "esgngdescription": "Core Id and Temporary Credentials generated and stored successfully." }
3	https://external-api- esgng- uat.preprod.fda.gov /api/esgng/v1/comp anies	Retrieve the user ID and list of companies and the associated company IDs for which a given user can create submissions	GET	Query Parameter: user_email = <u>testagent5@test.com</u> <b>Note: Please pass accesstoken in a header</b> Key – Values accesstoken - {accesstoken}	<pre>{     "user_id": 55,     "user_email":     "testagent5@test.com",     "company_id": 30,     "company_status": "Actual Agency",     "company_status": "Approved",     "authorizing_companies": [     {         "authorizing_company_id": 2,         "authorizing_company_name": "Oldio Corp"     },     {         "authorizing_company_id": 5,         "authorizing_company_id": 5,         "authorizing_company_name": "Fantastic Calm"     } }</pre>



No	API Endpoint	API Descriptio n (Industry Partners)	Request Method	Request Input (Sample values)	Request Output (Sample values)
					], "esgngcode": "ESGNG390", "esgngdescription": "Company Information retrieved successfully from ESGNG." }
4	https://external-api- esgng- uat.preprod.fda.gov /api/esgng/v1/subm issions/{core_id}	Retrieve submission status for a given core id	GET	URI Paramter: {core_id} -> CmpAssociatesInc_2023110733023 Note: Please pass accesstoken in a header Key – Values accesstoken - {accesstoken}	<pre>{     "core_id": "CmpAssociatesInc_2023110733023",     "status": "Upload Initiated",     "submission_protocol": "API",     "esgngcode": "ESGNG270",     "esgngdescription": "Submission status retrieved successfully." }</pre>
5	https://external-api- esgng- uat.preprod.fda.gov /api/esgng/v1/ackn owledgements/{cor e_id}	Retrieve all ACKs information and also to have a link for ACK3 file to download.	GET	URI Paramter: {core_id} -> CmpAssociatesInc_2023110733023 Note: Please pass accesstoken in a header Key – Values accesstoken - {accesstoken}	
6	https://upload-api- esgng- uat.preprod.fda.gov /rest/forms/v1/fileup load/payload	Insert payload.	GET	Do not supply a request body with this method.	{ "data" : { "payloadId" : "string", "uploadFileLink" : "string", "submitFormLink" : "string"



No	API Endpoint	API Descriptio n (Industry Partners)	Request Method	Request Input (Sample values)	Request Output (Sample values)
					} }
7	https://upload-api- esgng- uat.preprod.fda.gov /rest/forms/v1/fileup load/payload/:paylo adId/file	Upload one attachment at a time.	POST	Request Parameter payloadId	{ "data" : { "status" : "string", "message" : "string" } }
8	https://upload-api- esgng- uat.preprod.fda.gov /rest/forms/v1/fileup load/payload/:Payl oadid/submit	Submit the payload.	POST	Request body: { "username" : "string", "password" : "string", "sha256_checksum" : "string" }	{ "data" : { "message" : "string", "files" : [ { "id" : "string", "name" : "string", "size" : "string", "link" : "string" } ] }