



---

**Title: Establishment and Use of an FDA Electronic Submissions Gateway  
(ESG) Account**

SOP Number: 24302

**Revision Number: 06**

Supersedes: Revision 05

**Effective Date: AUG 26 2019**

---

Originator/Date:

Approval/Date:

Approval/Date:

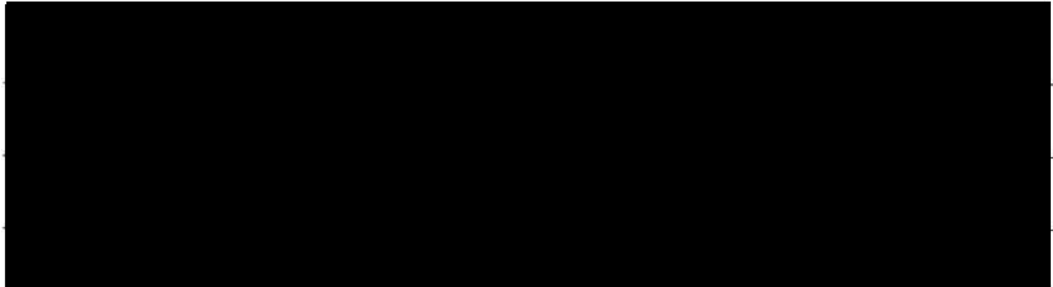


Table of Contents

- 1.0 Purpose
- 2.0 Scope
- 3.0 Authority and Responsibility
- 4.0 Electronic Submissions Gateway (ESG) Overview
- 5.0 FDA ESG Account Preparatory Activities
- 6.0 FDA ESG Test Account Registration
- 7.0 FDA ESG Production Account
- 8.0 Sending and Tracking Submissions Using the FDA ESG Production System
- 9.0 Documentation
- 10.0 Definitions
- 11.0 References and Related Documents
- 12.0 Attachments

1.0 Purpose

This procedure defines the process by which an FDA Electronic Submissions Gateway (ESG) account is established and utilized for submission of documents in electronic format to the FDA.

## **2.0 Scope**

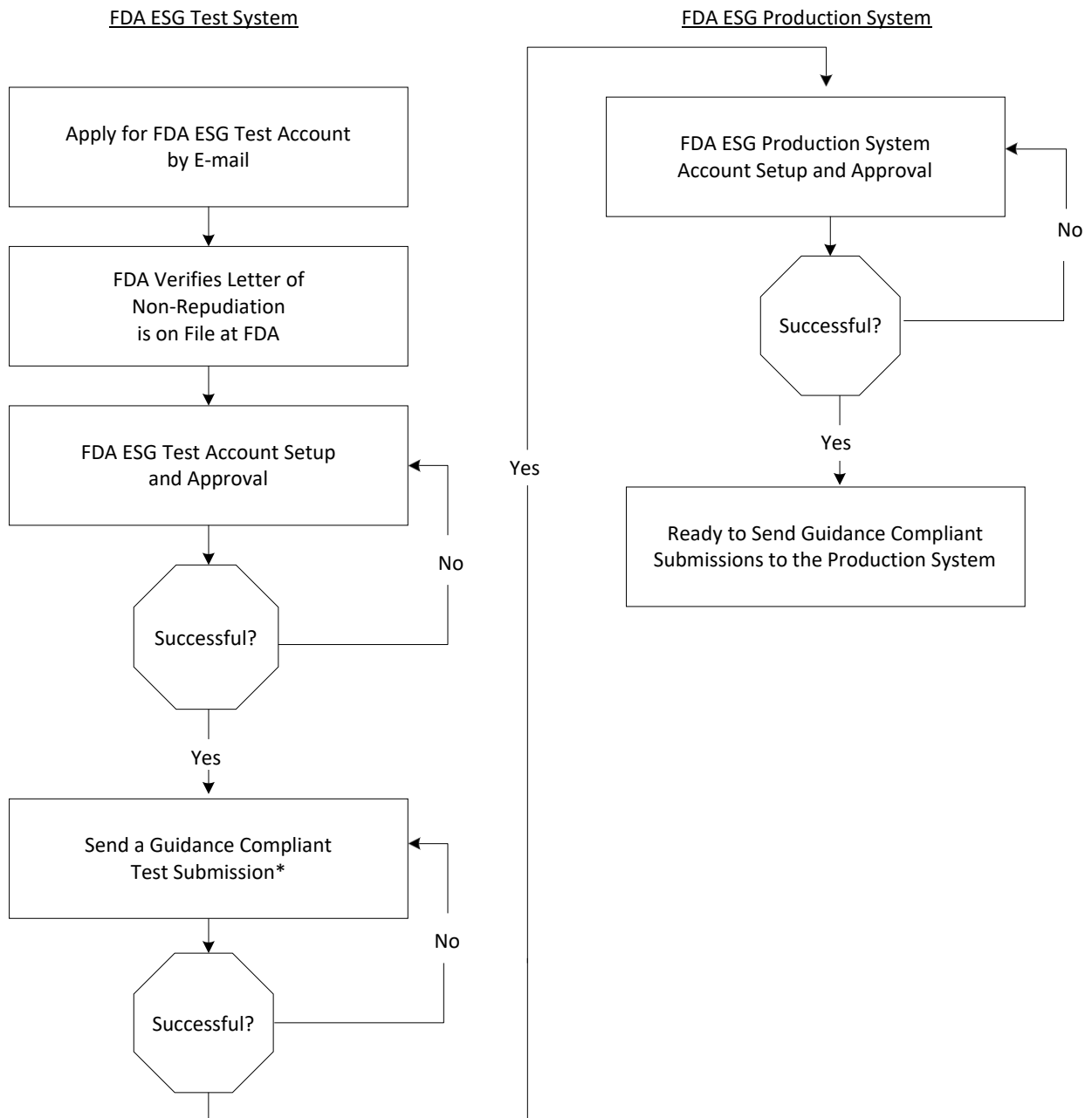
This procedure applies to Biopharmaceutical Development Program (BDP) personnel that are involved in the submission of documents in electronic format to the FDA using the ESG for Leidos Biomedical Research, Inc./National Cancer Institute (NCI) at Frederick.

## **3.0 Authority and Responsibility**

- 3.1 The Director, Biopharmaceutical Quality Assurance (BQA) has the authority to define this procedure.
- 3.2 The Leidos Biomedical Research Inc., /BDP Director, Regulatory Affairs is responsible for determining which BDP employees require an FDA ESG account.
- 3.3 BQA Regulatory Affairs employees or designees are individually responsible for the establishment and use of FDA ESG accounts for the submission of documents in electronic format to the FDA. The individual registering for the account has the responsibility of following this procedure.
- 3.4 The BQA Regulatory Affairs employees or designees are responsible for ensuring that documents submitted to the FDA using the ESG are organized properly following FDA established guidelines prior to document submission.

## **4.0 Electronic Submissions Gateway (ESG) Overview**

- 4.1 The FDA ESG enables a single point of entry for receiving and processing all electronic submissions in a highly secure environment. The BDP uses the WebTrader method for making submissions.
- 4.2 Registering to use the FDA ESG involves a sequence of steps that are to be conducted for each individual that will be sending submissions using the FDA ESG. The first steps include the establishment of an FDA ESG test account. Establishing a test account includes providing a letter of Non-Repudiation and obtaining personal digital certificates. After a successful test account registration, an FDA ESG production account is established.
- 4.3 An overview of the registration process is included in the figure below.



\* If your company already has a WebTrader Production Account, only a connectivity test is required.

## 5.0 FDA ESG Account Preparatory Activities

Refer to the most current version of the *FDA Electronic Submissions Gateway (ESG) User Guide* (available online at <http://www.fda.gov/Industry/about-esg/user-guide>) for additional details regarding preparatory activities. A checklist for setting up the account is available online at <https://www.fda.gov/industry/create-esg-account/setting-webtrader-account-checklist>.

### 5.1 Letter of Non-Repudiation.

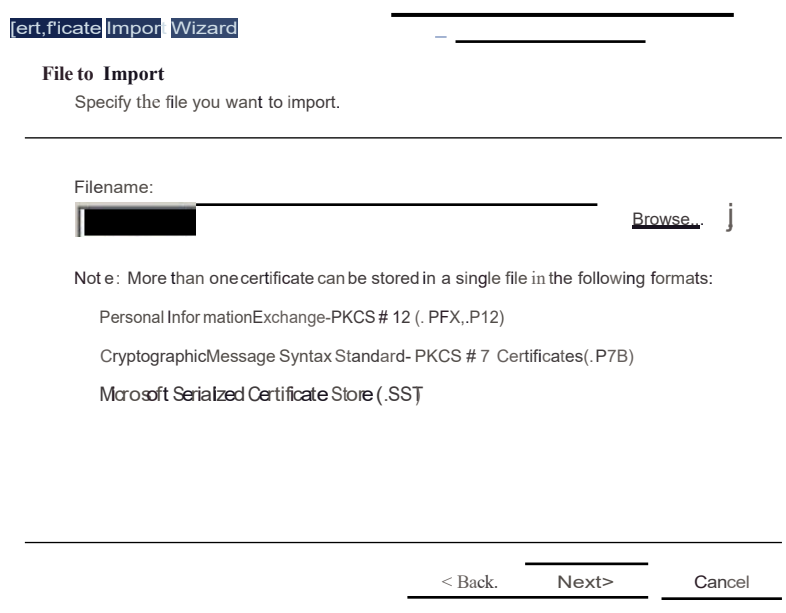
- 5.1.1 A non-repudiation agreement allows the FDA to receive electronically signed submissions in compliance with 21 CFR Part 11.100.
- 5.1.2 A letter of non-repudiation must be submitted to the FDA for each individual registering for an FDA ESG account. An example of a letter of non-repudiation is included in Attachment 1. Additional examples of non-repudiation letters can be found on the FDA ESG website.
- 5.1.3 Email the letter of non-repudiation to the ESG Help Desk, [ESGHELPDESK@fda.hhs.gov](mailto:ESGHELPDESK@fda.hhs.gov).

### 5.2 Digital Certificate

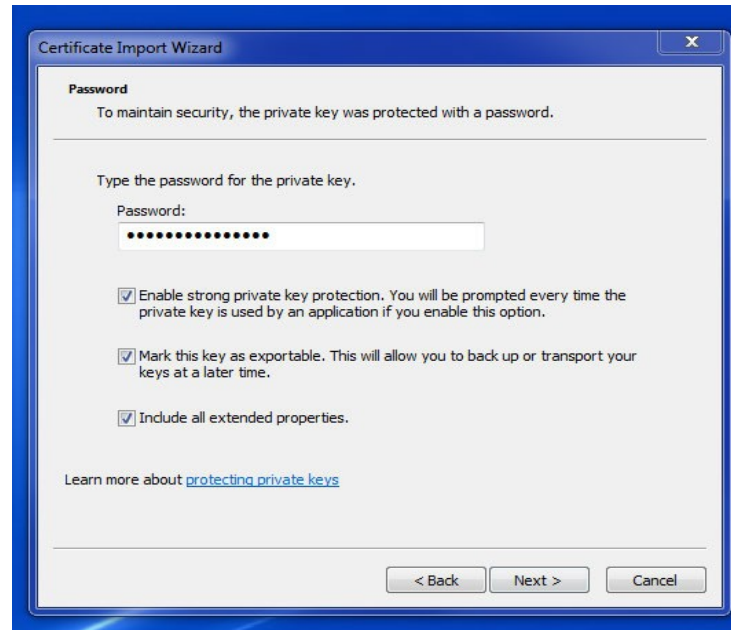
- 5.2.1 Digital certificates ensure private and secure submission of electronic documents. The digital certificate binds together the owner's name and pair of electronic keys (a public key and a private key) that can be used to encrypt and sign documents.
- 5.2.2 A digital certificate must be obtained for each individual registering for an FDA ESG account. A digital certificate binds the owners name and a pair of electronic keys (a public key and a private key) that can be used to encrypt and sign documents.
  - 5.2.2.1 A digital certificate can be obtained from either a public or private Certificate Authority (CA). GlobalSign is an example of an acceptable vendor.
  - 5.2.2.2 The digital certificate must be an X.509 Version 3 certificate and all data fields in the Issuer and Subject fields must be completed.
  - 5.2.2.3 Three-year expiration is recommended for digital certificates.
- 5.2.3 Depending on how the digital certificate is obtained, it must be exported to the computer control panel from which submissions to the FDA ESG will be made using the following procedure.
  - 5.2.3.1 Copy or download the digital certificate onto the computer drive where you want to store it.
  - 5.2.3.2 Double click the downloaded certificate file to open the certificate Import Wizard. Alternatively, you can contact the NCI at Frederick Computer Support Helpdesk (<http://css.ncifcrf.gov/helpdesk>) and place a helpdesk request.
  - 5.2.3.3 The "Certificate Import Wizard" window shown below will appear. Select the "Next" button to begin using the wizard.



- 5.2.3.4 The wizard will ask for the file name and location of the digital certificate (i.e., the computer file name). Click the "Browse" button. In the "Open" window that appears, change the "Files of type:" selection to "All Files (\*.\*)". Navigate to the location of the digital certificate and then click "Open". This will return you to the Certificate Import Wizard window. Click "Next" to continue. In the example below, the digital certificate is located on the [REDACTED]



- 5.2.3.5 Next, the wizard will ask for the password associated with the digital certificate. After entering the password, confirm that the three boxes are checked and then select the “Next” button.

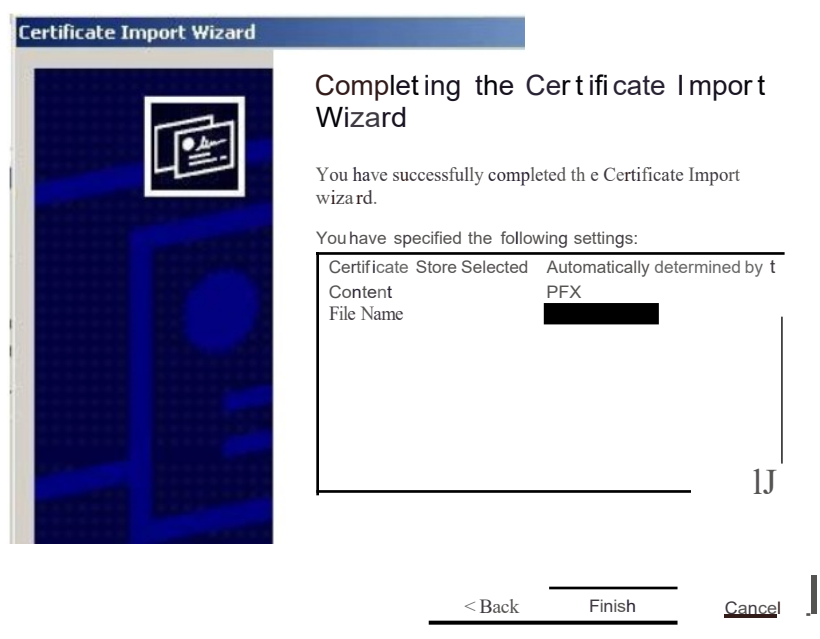


- 5.2.3.6 The wizard next asks for the location where the certificate is to be kept. Confirm the first choice is selected and then select the “Next” button.



This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [REDACTED]

- 5.2.3.7 To complete the "Certificate Import Wizard", select the "Finish" button as shown below. The digital certificate now resides in the control panel.

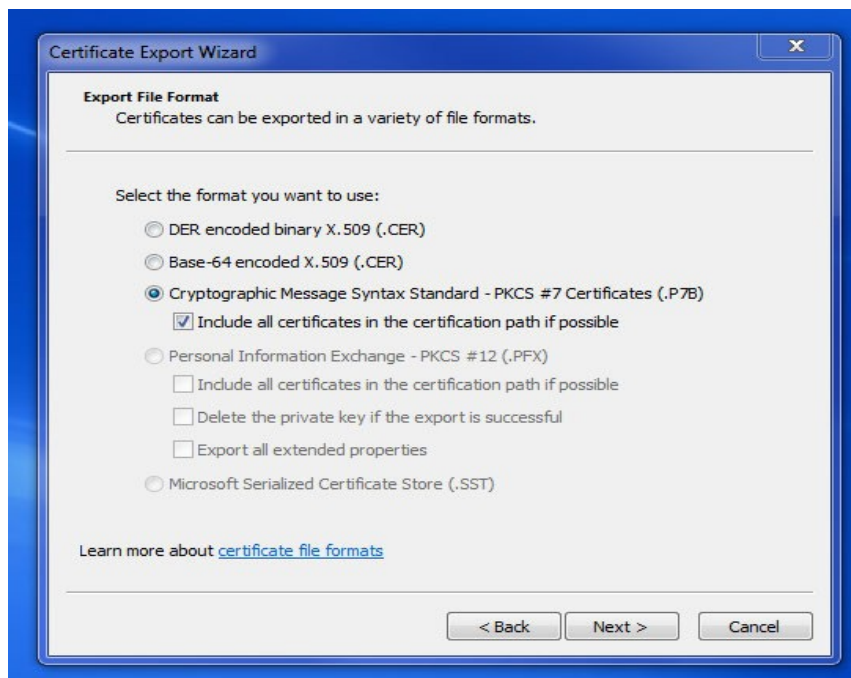


- 5.2.4 After importing the digital certificate from an external source to the PC control panel the digital certificate must be exported to create public and private keys as described in the following steps. The FDA ESG website can be referenced for information on how to download digital certificates at <https://www.fda.gov/industry/about-esg/esg-appendix-c-digital-certificates>. Note that some of the information on the FDA website may not apply to your system so consult the NCI at Frederick Help Desk, if needed.
- 5.2.5 To export the public key (.p?b):
- 5.2.5.1 Either contact the NCI at Frederick Computer Support Helpdesk (<http://css.ncifcrf.gov/helpdesk>) and place a helpdesk request for support, or you can go to the start menu and type "certmgr.msc" in the search field and hit enter.
    - 5.2.5.1.1 If you choose to use the "certmgr.msc" function, double click on the personnel folder and then the certificates folder.
    - 5.2.5.1.2 Right click on the certificate file that should have been downloaded to your computer (current date) and choose "All tasks", and then export. This will open the certificate Export Wizard.
    - 5.2.5.1.3 The "Certificate Export Wizard" is displayed. This wizard will guide you through the remainder of the export process. Click "Next" to begin.

- 5.2.5.1.4 In the “Export Private Key” window, select “No, do not export the private key” and then click “Next”.



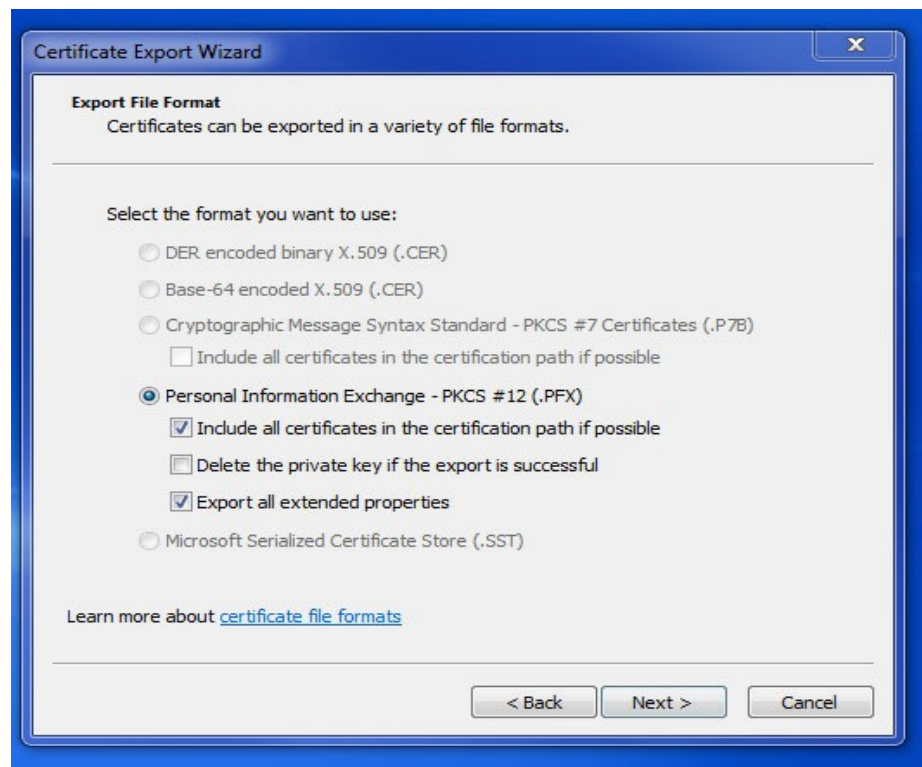
- 5.2.5.2 In the “Export File Format” window, select “Cryptographic Message Syntax Standard – PKCS #7 Certificates (.P7B)”. Check the box that says, “Include all certificates in the certification path if possible”. Then click “Next” to continue.



This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [REDACTED]



- 5.2.5.3 Name the certificate file and select a location to save the file. Using your name, the term “public key”, and the key expiration date (YYYYMMDD) in the name of the certificate file can be helpful. Example: “XXXXXXXXXX”.
- 5.2.5.4 Click “Next” and then “Finish”. The public key is now ready for use.
- 5.2.6 To export the private key (.PFX):
  - 5.2.6.1 Either contact the NCI at Frederick Computer Support Helpdesk (<http://css.ncifcrf.gov/helpdesk>) and place a helpdesk request for support, or you can go to the start menu and type “certmgr.msc” in the search field and hit enter.
    - 5.2.6.1.1 If you choose to use the “certmgr.msc” function, double click on the personnel folder and then the certificates folder.
    - 5.2.6.1.2 Right click on the certificate file that should have been downloaded to your computer (current date) and choose “All tasks”, and then export. This will open the certificate Export Wizard.
    - 5.2.6.1.3 The “Certificate Export Wizard” is displayed. This wizard will guide you through the remainder of the export process. Click “Next” to begin.
    - 5.2.6.1.4 In the “Export Private Key” window, select “Yes, export the private key” and then click “Next”.
    - 5.2.6.1.5 In the “Export File Format” window, select “Personal Information Exchange – PKCS #12 (.PFX)” and check both “Include all certificates in the certification path if possible” and “Export all extended properties”. Click “Next” to continue.



5.2.6.2 Enter and confirm a password for your private key. Click “Next” to continue.



This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract XXXXXXXXXX

- 5.2.6.3 In the "File to Export" window, name the certificate file and select a location to save the file. Using your name, the term "private key", and the key expiration date (YYYYMMDD) in the name of the certificate file can be helpful. Example: '[REDACTED]'



- 5.2.6.4 Click "Next". On the next screen click "Finish" and then "OK".

### 5.3 Updating a Digital Certificate to an Existing ESG Account

- 5.3.1 Obtain a new digital certificate from either a public or private Certificate Authority (CA).
- 5.3.2 Follow the Steps 5.2.3 - 5.2.6 to export the public and private keys.
- 5.3.3 Email the public key (.p7b or .cer) to [ESGHelpDesk@fda.hhs.gov](mailto:ESGHelpDesk@fda.hhs.gov), and provide the name of the primary account holder, and the electronic submissions gateway account name.
- 5.3.4 A confirmation email will be received from [ESGHelpDesk@fda.hhs.gov](mailto:ESGHelpDesk@fda.hhs.gov) notifying the account holder that the new public key has been uploaded. Submissions may then be sent via the ESG using the newly exported private key (.pfx).

### 5.4 Electronic Submission Guideline Requirements.

- 5.4.1 A detailed list of electronic submissions supported by the FDA ESG can be found on the FDA's website in the FDA Electronic Submissions Gateway (ESG) User Guide at <https://www.fda.gov/industry/about-esg/esg-chapter-3-preparatory-activities#3>2>2> (Section 3.3 Table 2).
- 5.4.2 Each FDA center has specific guidelines that must be followed for the successful submission of electronic documents. Refer to the FDA's website for FDA ESG User Guide at <https://www.fda.gov/industry/about-esg/esg-chapter-3-preparatory-activities#3>2>2> (Section 3.3 Table 1).

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [REDACTED]

- 5.4.3 Additional information for the preparation and organization of compliant electronic documents at the BDP is included in ***SOP 24412 - Preparation of a Type V Facilities Electronic Master File (eCTD Format)*** and ***SOP 24410 - Preparation of Amendments to a Type V Facilities Electronic Drug Master File (CBER Format)***.

## 5.5 Submission Method and Connection Requirements

- 5.5.1 FDA ESG submissions are sent using the FDA ESG Web Trader Interface submission method. This is the preferred BDP submission method. For other submission methods refer to the current ESG User Guide.
- 5.5.2 FDA ESG WebTrader Interface requires the following (IT assistance may be required to verify the below requirements are met):
- A high-speed internet connection.
  - A web browser: Internet Explorer 11 or above, Mozilla Firefox, or Google Chrome.
  - Hard disk space of at least three times the size of the submission. For instance, if the submission is 1MB in size, then at least 3MB of hard disk space is required.
- 5.5.3 Before beginning the registration process, the following information should be known:
- Company and contact information (the company name is "Leidos Biomedical Research Inc.," followed by the individual's name so that multiple users from the same company each have a unique identifier). For example, "Leidos Biomedical Research Inc. /Samantha Smith". This will be the account name.
  - Your Digital Certificate file location.

## 6.0 FDA ESG Test Account Registration

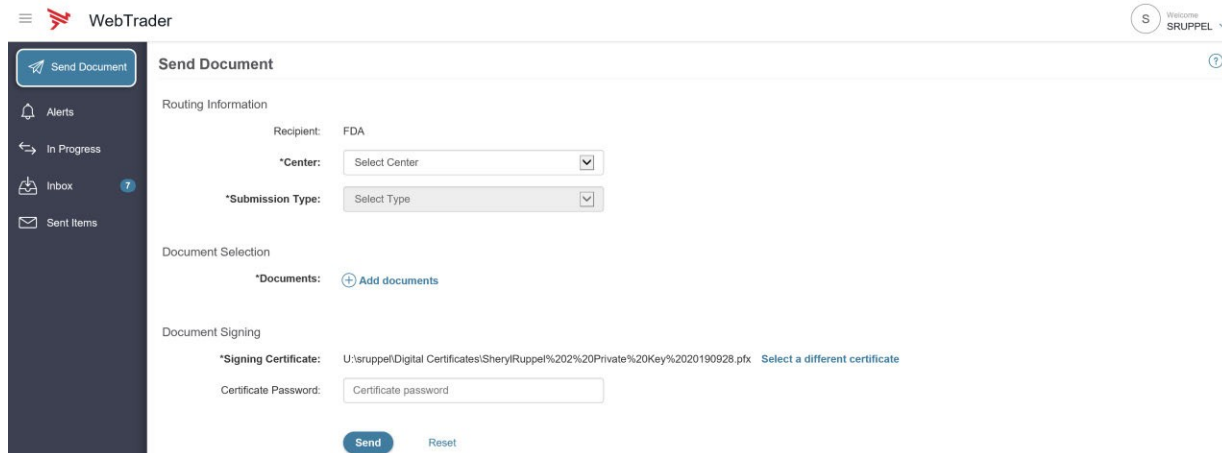
Refer to the *FDA Electronic Submissions Gateway (ESG) User Guide* for additional details regarding FDA ESG Test Account registration.

A checklist for how to register for an account and on how to set up and use the FDA ESG Web Interface is available on the FDA's ESG website

(<https://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/CreateanESGAccount/ucm114831.htm>).

- 6.1 The registration process is initiated by emailing the FDA ESG Help Desk ([ESGHelpDesk@fda.hhs.gov](mailto:ESGHelpDesk@fda.hhs.gov)) and indicating your intent to register for the FDA ESG WebTrader test account. The subject of the email should be "New WebTrader Test Account Registration". Include your company name (as established in Step 5.5.3), your name, phone number, submission method (WebTrader), and attach your letter of Non-Repudiation.

- 6.2 Follow the current FDA Electronic Submissions Gateway User Guide for the current procedures to register for a test account. Tutorials are also available on the FDA ESG web site.
- 6.3 After a successful Test Account setup, the FDA will send an email to the email address provided for the applicant, indicating account activation. Follow the instructions for pre-production set-up.
- 6.4 After Test Account Setup, a test submission must be sent to ensure that the submission "conduit" is working properly from end to end. Reference the ESG User Guide for more information.
- 6.4.1 From the "Send Document" page, select CBER from the "Center" drop-down menu. From the "Submission Type" drop-down menu (automatically populated with the correct submission types for the selected Center), select "eDMF".



- 6.4.2 Select the "Add documents" link to add the file(s) that will be sent as the test submission. Select the drive and navigate to the file to be sent. Ensure the test submission is a guidance compliant document. (For the test submission, use the compliant submission folder found at [REDACTED] DMF 6298/ESG Test Submission/Compliant Submission.)

**NOTE:** If your company already has a Production WebTrader account, send a test submission to the center labeled "GWTEST" and the submission type labeled "ConnectTest". After you receive an Acknowledgement, send an email to [ESGHelpDesk@fda.hhs.gov](mailto:ESGHelpDesk@fda.hhs.gov) with the Acknowledgement's Core ID.

- 6.4.3 All submissions require a certificate to digitally sign and encrypt the submission. Select a signing certificate by clicking the "Browse..." button and selecting your Private Key. Note that the Private Key signing certificate is the .PFX certificate created in Step 5.2.6. Fill in the certificates password. This is the password created in Step 5.2.6.2
- 6.4.4 Click the "Send" button on the "Send Document" page.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [REDACTED]

- 6.4.5 When the submission is successfully received at the FDA, a receipt email will be listed in the "Inbox". The receipt for the test submission should be displayed under the "Document Name" column as a hyperlink. Click on the hyperlink to open the receipt. If the submission was successfully delivered this will be indicated under the status. You may print the receipt for documentation purposes using the printer icon on the right of the window.

The screenshot shows the WebTrader interface with a sidebar on the left containing 'Send Document', 'Alerts', 'In Progress', 'Inbox' (with a notification badge), and 'Sent Items'. The main area displays an 'Inbox' with 8 results. A table lists documents with columns for Document Name, Status, Date, File Size, and Type. A 'Document Details' window is open, showing details for a receipt document.

Document Name	Status	Date	File Size	Type
Receipt	Received	Aug 29th 2018, 1:06:50 pm	304 bytes	Acknowledgement
Receipt	Received	Aug 29th 2018, 12:56:43 pm	2 KB	Receipt
Receipt	Received	Jun 2nd 2017, 4:16:28 pm	326 bytes	Acknowledgement
Receipt	Received	Jun 2nd 2017, 4:09:53 pm	2 KB	Receipt
Receipt	Received	Apr 13th 2016, 12:55:04 pm	323 bytes	Acknowledgement
Receipt	Received	Apr 13th 2016, 12:49:51 pm	2 KB	Receipt
Receipt	Received	Apr 28th 2014, 11:59:45 am	315 bytes	Acknowledgement
Receipt	Received	Apr 28th 2014, 11:53:25 am	2 KB	Receipt

**Document Details**

''' Receipt

FileName: Receipt\_010019.tar.gz.txt

Status: Received

Date: Aug 28th 2018 1:06:50 pm

File Size: 2 KB

Submitted: 00:00:00

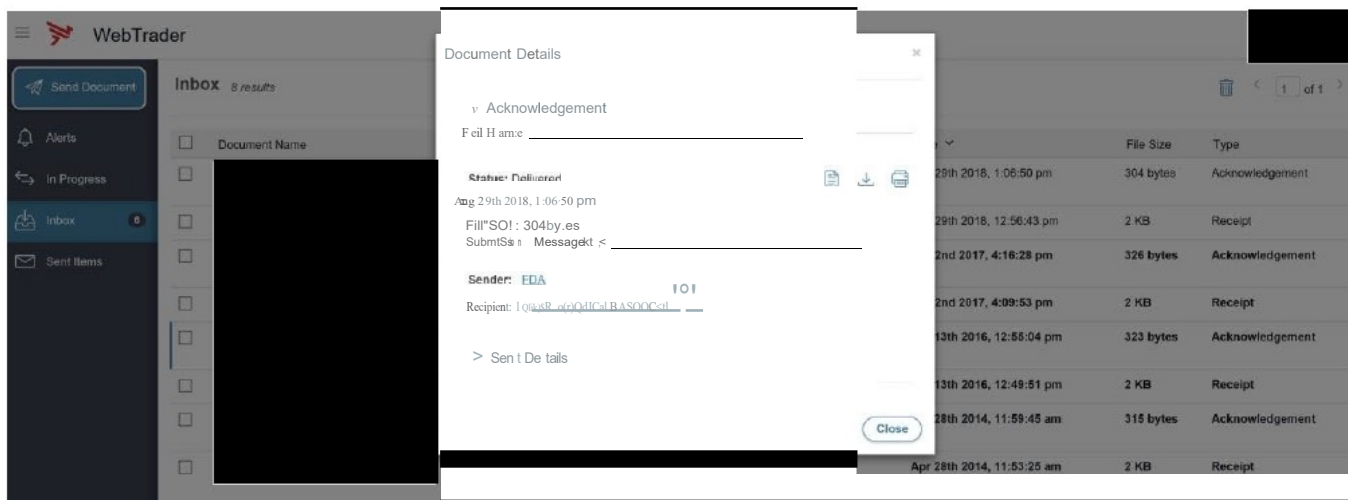
Sender: [Redacted]

Recipient: [Redacted]

> Send Details

Close

- 6.4.6 The FDA ESG will then route the test submission to the Center Holding Area. When the Center successfully receives the submission, an acknowledgement will be listed on the "Inbox" page. The acknowledgement for the test submission should be displayed here as a hyperlink in the "Document Name" column. Click on the hyperlink to open the acknowledgement. You may print the acknowledgement for documentation purposes using the printer icon on the right of the window.



6.4.7 Once you have sent a successful submission or connectivity test, your account will be migrated to production. You will receive an e-mail from the FDA Help Desk with production account confirmation and production URL.

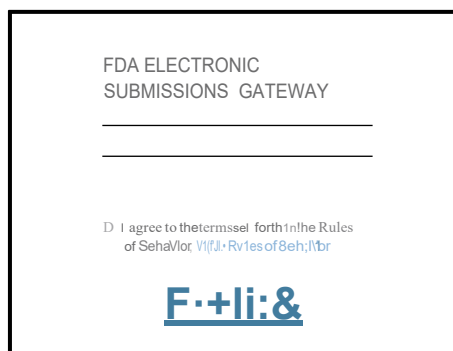
## 7.0 FDA ESG Production Account

7.1 Once you are migrated to the production account, navigate to the URL for the FDA ESG: <https://esg.fda.gov> and log in using the User ID and Password you created for the test account. You are now ready to send electronic submissions to the FDA using the ESG system.

## 8.0 Sending and Tracking Submissions Using the FDA ESG Production System

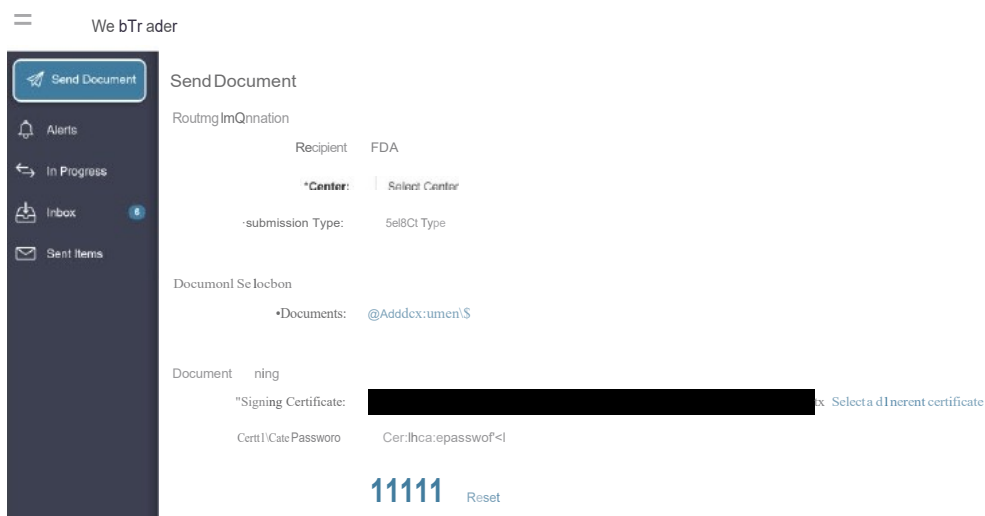
Refer to the most current version of the *FDA Electronic Submissions Gateway (ESG) User Guide* (available online at <https://www.fda.gov/industry/about-esg/user:9uide>) for additional details regarding preparatory activities.

- 8.1 A submission cannot be sent to the production system until the notification described in Step 6.4.7 has been received.
- 8.2 Using the address provided by the FDA (<https://esg.fda.gov>), access the FDA ESG WebTrader and enter the User ID and Password set up for your production account. Click the "Login" button after agreeing to the terms set forth in the System Notification statement.



[ESG Web Help](#) [FAQs](#) [System Status](#)

- 8.3 After a successful login, the WebTrader page is displayed. Click the "Send Document" button on the left side of the screen.



- 8.4 From the "Send Document" screen, select an FDA Center from the "Center" drop-down menu. The eDMF is submitted to CBER. The "Submission Type" drop-down menu will be automatically populated with the correct submission types for the selected Center.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [REDACTED]



- 8.5 Select the type of submission under the “Submission Type” drop-down box. For example, “eDMF”.
- 8.6 Under the “Document Selection” section, click the “Add Documents” hyperlink. Choose the system drive (example █████ and folder where the submission is located (example: “DMF6298/006298/0019”). Click the “select button” at the bottom of the window with the folder highlighted.
- 8.7 All submissions require a certificate to digitally sign and encrypt the submission. Select a signing certificate by clicking the “Browse” button and selecting your Private Key (if you have already sent a document the certificate file path may already be displayed). Confirm the correct certificate file path is displayed. Note that the Private Key signing certificate is the .PFX certificate created in Step 5.2.6.
- 8.8 Enter the certificate password in the “Certificate password” dialog box displayed below the signing certificate.
- 8.9 Click the “Send” button on the “Send Document” page.
- 8.10 Once a submission has been sent using the FDA ESG WebTrader, a receipt and two acknowledgements are delivered to the account from which the submission was sent. These can be accessed on the “Sent Items” page.
- 8.10.1 A receipt from the FDA, also known as a Message Delivery Notification (MDN) is sent to the inbox of the account from which the submission was received. The file can be opened by clicking on the document name that appears as a hyperlink. This message denotes that the submission has been delivered to the FDA ESG. The MDN contains the message ID, a date/time stamp for the submission, delivery status, and file size. These items may be used to track a submission.
- 8.10.2 When a center receives a submission, it sends two acknowledgements to the Inbox of the ESG account from which the submission was sent. The date and time stamps convey on the first acknowledgement when the center has received and unpackaged the submission, and the second acknowledgement is received after the submission has been validated. The acknowledgements can be opened by clicking on the document name that appears as a hyperlink in the ESG account Inbox. This file is named with a Core message ID. This Core message ID may also be used to track a submission.
- 8.10.3 To document the submission, print the receipt and the acknowledgements as pdf files and save them as follows:
- For BDP DMF 6298: In the file path █████, create a subfolder. The subfolder should be named “█████”.
  - For other electronic submissions create a similar subfolder in the project file.
  - Save the pdf copy of both the receipt and the acknowledgements in the subfolder.

A paper copy may also be printed and filed in the DMF Regulatory Correspondence File for each project.

8.10.4 After the receipt and acknowledgements have been filed, the record can be deleted from the ESG page.

## 9.0 Documentation

- 9.1 Record the process of setting up FDA ESG test and production accounts, including e-mail and telephone correspondence with the FDA, on Form 24300-01, BDP Regulatory Contact Form as per **SOP 24300 - Communication with Regulatory Agencies**.
- 9.2 Record e-mails and/or telephone correspondence with the FDA regarding the use of established FDA ESG accounts on Form 24300-01, BDP Regulatory Contact Form.
- 9.3 A record of documents sent to the FDA electronically using the FDA ESG will be included in the appropriate Regulatory Correspondence file as described in **SOP 24409 - Preparation of a Type V Facilities Electronic Master File (CBER Format)** and **SOP 24410 - Preparation of Amendments to the Type V Facilities Electronic Drug Master File (CBER Format)**.
  - 9.3.1 A copy of the receipt and acknowledgement from the Center to which the submission was sent must be printed and included in the Regulatory Correspondence file for each submission.

## 10.0 Definitions

- 10.1 **Acknowledgment** – Verification that the submission was sent from the sender's system and received by the Gateway.
- 10.2 **Digital Certificate** – An electronic document which conforms to the International Telecommunications Union's X.509 specification. It contains the owner's name and public key, the expiration date of the public key, the serial number of the certificate, and the name and digital signature of the organization which issued the certificate. It binds together the owner's name and a pair of electronic keys (public and private) that can be used to encrypt and sign documents.
- 10.3 **Digital Signature** – A process that can be used to attach a digital code to an electronic message that is unique to the individual signing the message. A digital signature results from the use of a "Private Key" to apply a signature to an electronic message. The "Public Key" on file with the recipient of the electronic message can be used to verify whether or not the digital signature is valid, and whether the message has been altered since it was signed.
- 10.4 **Electronic Submissions Gateway (ESG)** – The central transmission point for sending information electronically to the FDA. The FDA ESG is a "highway" along which submissions travel to reach their final destination. It does not open or review submissions, it merely routes them to the proper destination.
- 10.5 **Electronic Submission Process** – The receipt, acknowledgement, routing, and notification to a receiving Center of the receipt of an electronic submission.

- 10.6 **Non-Repudiation** – The concept of ensuring that one cannot repudiate, or refuse to acknowledge, ratify, or recognize as valid. A common application is in the verification and trust of signatures. 21 CFR 11.100 requires that “persons using electronic signatures shall, prior to or at the time of such use, certify to the agency that the electronic signatures in their system, used on or after August 20, 1997, are intended to be the legally binding equivalent of traditional handwritten signatures”.
- 10.7 **Notification** – Notice of a submission’s arrival is made to those individuals responsible for the Center’s receiving system.
- 10.8 **Receipt** – Transfer of a submission from a sender’s system to a temporary storage area in the FDA ESG.
- 10.9 **Routing** – Delivering a submission to a Center-level storage area and initiating a load process to place a submission into a Center receiving system.

## 11.0 References and Related Documents

- 11.1 **SOP 24300**      *Communication with Regulatory Agencies*
- 11.2 **SOP 24409**      *Preparation of a Type V Facilities Electronic Master File (CBER Format)*
- 11.3 **SOP 24410**      *Preparation of Amendments to the Type V Facilities Electronic Drug Master File (CBER Format)*
- 11.4 *FDA Electronic Submissions Gateway (ESG) User Guide, 07/31/2018 (or current effective User Guide found at <http://www.fda.gov/electronic-submissions-gateway> (or <http://www.fda.gov/Industry/about-esg/user-guide>).*

## 12.0 Attachments

- 12.1 **Attachment 1**      Sample Letter of Non-Repudiation

**Attachment 1**  
**Sample Letter of Non-Repudiation**

[REDACTED]

May 16, 2007

Office of Regional Operations (HFC-100)

[REDACTED]

Re: Electronic Signatures

Dear Sir or Madam:

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that -- Inc., Frederick, Maryland 21702-1201 intends that electronic signatures executed by our employees, [REDACTED] and [REDACTED] are the legally binding equivalent of traditional hand-written signatures.

Sincerely,

[REDACTED]

[REDACTED]

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

1km

[REDACTED]

[REDACTED]