

Electronic Submissions Gateway (ESG)

System and Program Overview

May 2018

Agenda

- What is the ESG?
- How do you send submissions to ESG?
- How does ESG work?
- How do you register for ESG?
- How does ESG use Digital Certificates?
- How do you use WebTrader?
- Are there account limitations?
- What is the Help Desk support process?
- ESG Resources

What is ESG?

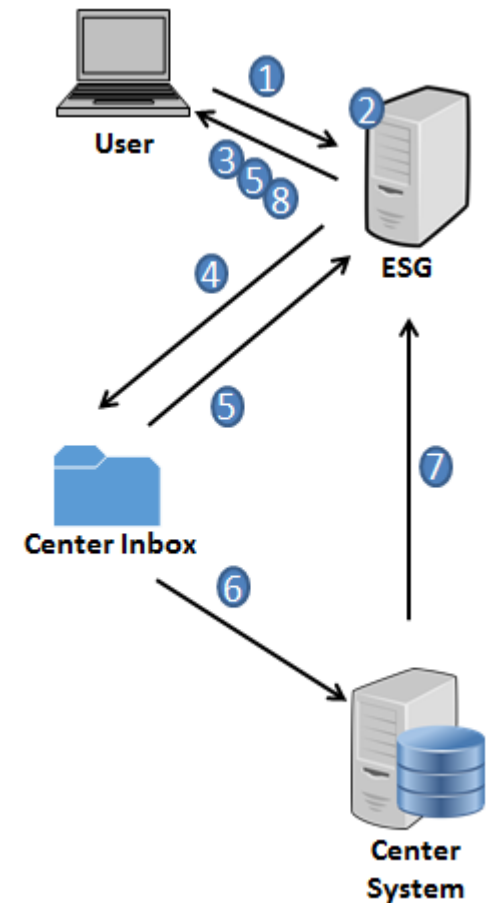
- The Food and Drug Administration (FDA) Electronic Submissions Gateway (ESG) is an Agency-wide solution for accepting electronic regulatory submissions. The FDA ESG enables the secure submission of premarket and postmarket regulatory information for review.
- The FDA ESG is the central transmission point for sending information electronically to the FDA. Within that context, the FDA ESG is a conduit along which submissions travel to reach the proper FDA Center or Office.

How do you send submissions to ESG?

- **WebTrader:** WebTrader is a web-based interface used to send submissions and receive receipts and acknowledgments from the FDA. The WebTrader application makes communication with the FDA simple, cost-effective, and time-independent. All Submissions are signed using PKI certificates.
- **System-to-System (AS2):** Users have the option to send submissions to FDA Gateway via system-to-system communication. System-to-system communication (often referred to as an AS2 Account) provides an automated connection to the FDA for submissions, receipts and acknowledgments. The system-to-system communication requires a server(s) and software procurement and configuration from users. All Submissions are signed using PKI certificates. AS2 users can also encrypt submissions.
- The FDA ESG uses Applicability Statement 2:
 - Specification about how to transport data securely and reliably
 - Security is achieved by using digital certificates and encryption
 - All submission receive a MDN

How does ESG Work?

1. User sends single file or folder submission to FDA via HTTPs
2. ESG receives the submission and validates signature
3. FDA ESG sends a Receipt to the submitter
4. The submission is assigned unique ID and is transferred to the Center Inbox
5. An Acknowledgement (ACK 2) is generated and sent to the submitter
6. The Center downstream system validates and processes the submission from the Center Inbox
7. The Center generates and sends additional Acknowledgements (ACK 3) to ESG
8. ESG sends Center Acknowledgements to Submitter



How do you register for ESG?

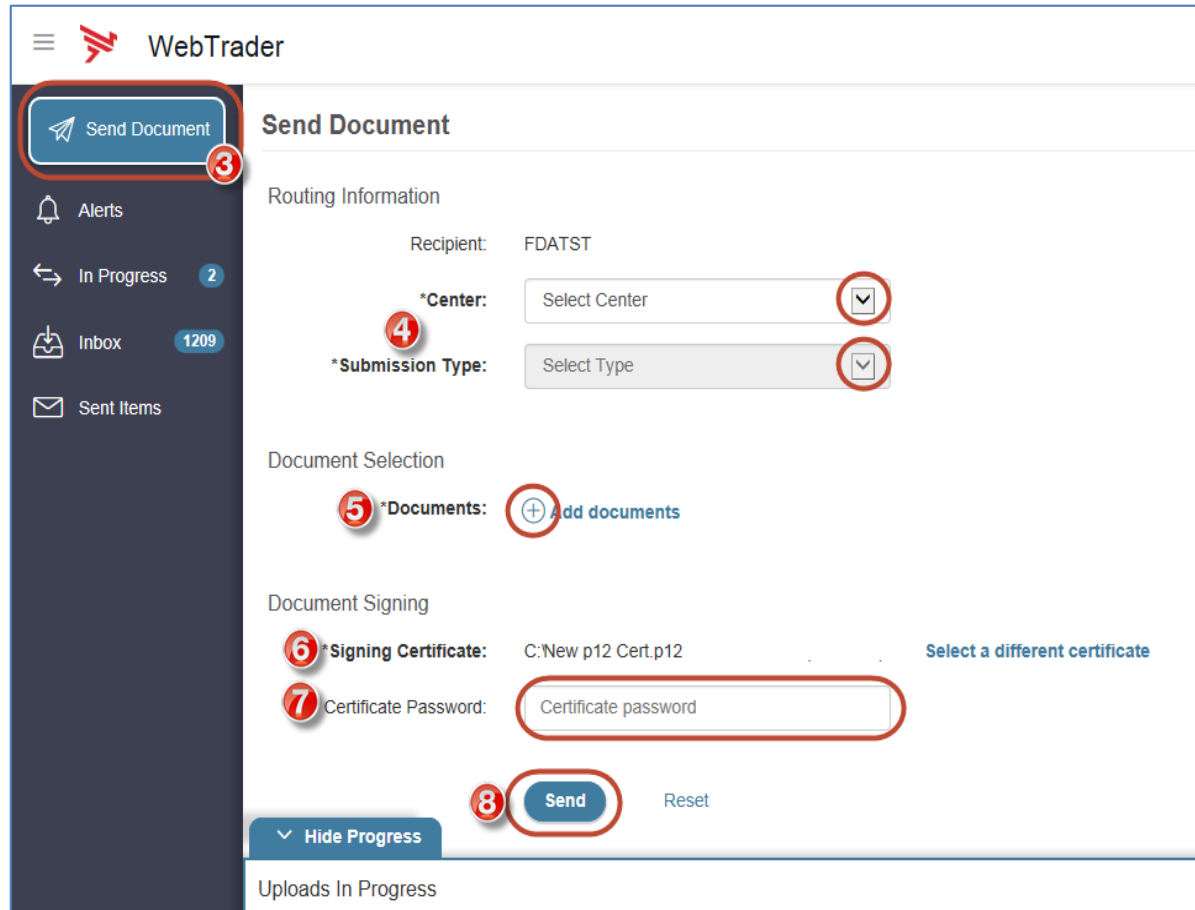
- Send an Account Request to: ESGHelpDesk@fda.hhs.gov
- ESG will send Registration Instructions
- Send Letter of Non Repudiation
- Obtain Digital Certificate
- Register for an ESG Account
- ESG will review, process Account Registration, and send further instructions based on Account Type
- Send a Test submission(s)
- Center validates test results and notifies ESG of results
- ESG Migrates Account to Production upon successful test
- A complete checklist can be found on the ESG Website

How does ESG use Digital Certificates?

- ESG uses digital certificates to electronically sign digital submissions
- User registers with Public Key
- User sends submission with Private Key
- ESG uses Public Key to unlock the submission securely
- ESG uses digital certificates that conform to X.509 specification
- Digital Certificate contains the
 - owner's name
 - email address
 - expiration date
 - serial number
 - name of the organization
 - The digital certificate binds a pair of electronic keys that can be used to encrypt and sign documents
 - Expiration may be from 1 to 3 years

How do you use WebTrader?

1. Go to [WebTrader site](#)
2. Login with User ID and Password
3. Click on “Send Document”
4. Select Center and Submission Type
5. Select file / folder
6. Select Digital Certificate
7. Insert Certificate Password
8. Click “Send” button
9. For more info go to [Tutorial](#)



The screenshot shows the 'Send Document' page in the WebTrader application. The interface includes a left-hand navigation menu with options like 'Send Document', 'Alerts', 'In Progress', 'Inbox', and 'Sent Items'. The main content area is titled 'Send Document' and contains several sections: 'Routing Information' with fields for 'Recipient' (FDATST), '*Center' (a dropdown menu), and '*Submission Type' (a dropdown menu); 'Document Selection' with a '+ Add documents' button; 'Document Signing' with fields for '*Signing Certificate' (C:\New p12 Cert.p12) and 'Certificate Password' (with a password input field); and a 'Send' button. Red circles with numbers 1 through 8 are overlaid on the interface to indicate the steps: 1. 'Send Document' button; 2. 'In Progress' button; 3. 'Send Document' button; 4. '*Center' dropdown; 5. '+ Add documents' button; 6. '*Signing Certificate' field; 7. 'Certificate Password' field; 8. 'Send' button.

How do you use WebTrader? - Continued

- How to download Acknowledgements:

1. Click on “Sent Items” in left pane
2. Click on a submission link
3. A pop-up window will appear
4. Click on link to View, Download, or Print

WebTrader

Sent Items 589 results

Status	Document Name	Receipt	Acknowledgements
<input type="checkbox"/>	Delivered	GB 6.tar.gz	Receipt Acknowledgements
<input type="checkbox"/>	Delivered	GB 6.tar.gz	Receipt Acknowledgement
<input type="checkbox"/>	Delivered	test DO NOT PROCESS.tar.gz	Receipt Ack
<input type="checkbox"/>	Delivered	test DO NOT PROCESS.txt	Receipt Acknow

Document Details

▼ Acknowledgement

File Name: ci1524679928395.160086@fdsuv05638_te1.txt

Status: Delivered

Date: Apr 27th 2018, 9:54:54 am

File Size: 299 bytes

Submission Message Id: <131344688.4.1524674089754@OCL0164415>

Sender: [FDATST](#)

How do you use WebTrader? - Continued

- How to delete Submissions:

1. Click on “Sent Items” in left pane
2. Place a check next to the submissions to be deleted
3. Click the trash can
4. A pop-up window will appear, you must confirm deletion

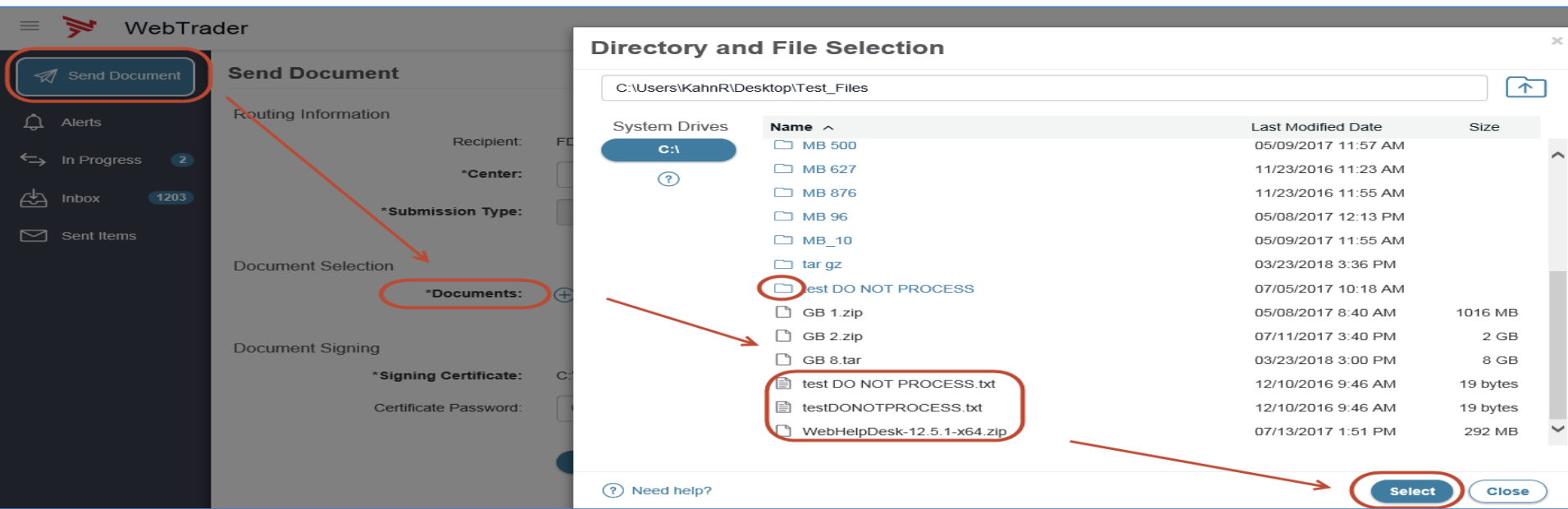
WebTrader

Sent Items 589 results

<input type="checkbox"/>	Status	Document Name	Center	Type	File Size	Date
<input type="checkbox"/>	Delivered	GB 6.tar.gz Receipt 2 Acknowledgements	GWTEST	ConnectTest	6 GB	Apr 25th 2018, 12:34:49 pm
<input type="checkbox"/>	Delivered	GB 6.tar.gz Receipt Acknowledgement	GWTEST	ConnectTest	6 GB	Apr 25th 2018, 9:14:30 am
<input type="checkbox"/>	Delivered	test DO NOT PROCESS.tar.gz Receipt Acknowledgement	CBER	eDMF	3 KB	Apr 5th 2018, 1:34:35 pm
<input type="checkbox"/>	Delivered	test DO NOT PROCESS.txt Receipt Acknowledgement	CBER	eDMF	3 KB	Apr 5th 2018, 1:33:27 pm
<input type="checkbox"/>	Delivered	Transfer_CFT_3.2.4_Install_win-x86-64_BN10690000.zip Receipt Acknowledgement	GWTEST	ConnectTest	170 MB	Mar 14th 2018, 3:56:08 pm
<input type="checkbox"/>	Delivered	test DO NOT PROCESS.txt Receipt Acknowledgement	CBER	eDMF	3 KB	Mar 14th 2018, 1:02:07 pm
<input checked="" type="checkbox"/>	Delivered	test DO NOT PROCESS.txt Receipt Acknowledgement	CBER	eDMF	3 KB	Mar 14th 2018, 9:41:19 am
<input checked="" type="checkbox"/>	Delivered	test DO NOT PROCESS.tar.gz Receipt Acknowledgement	CBER	eDMF	3 KB	Mar 14th 2018, 9:40:23 am
<input checked="" type="checkbox"/>	Delivered	test DO NOT PROCESS.txt Receipt Acknowledgement	CBER	eDMF	3 KB	Mar 14th 2018, 9:28:08 am

How do you use WebTrader? - Continued

- How to make multiple Submissions at the same time:
 1. Click on “Send Document” in left pane
 2. For multi-file, click on folder icon (not name)
 3. For single file, click on folder icon or name
 4. Click the “Select” button
 5. Continue with the steps from slide 8



WebTrader

Send Document

Routing Information

Recipient: FD

*Center:

*Submission Type:

Document Selection

*Documents:

Document Signing

*Signing Certificate:

Certificate Password:

Directory and File Selection

C:\Users\KahnR\Desktop\Test_Files

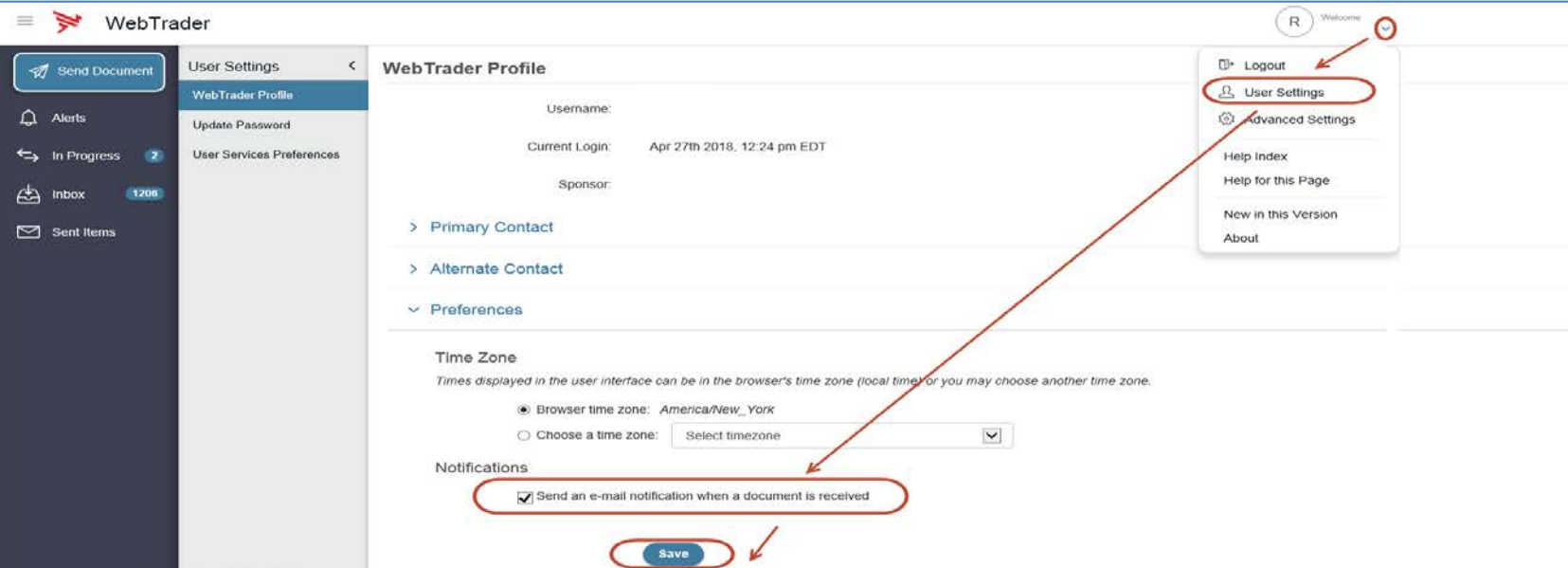
System Drives	Name ^	Last Modified Date	Size
C:\			
	MB 500	05/09/2017 11:57 AM	
	MB 627	11/23/2016 11:23 AM	
	MB 876	11/23/2016 11:55 AM	
	MB 96	05/08/2017 12:13 PM	
	MB_10	05/09/2017 11:55 AM	
	tar gz	03/23/2018 3:36 PM	
	test DO NOT PROCESS	07/05/2017 10:18 AM	
	GB 1.zip	05/08/2017 8:40 AM	1016 MB
	GB 2.zip	07/11/2017 3:40 PM	2 GB
	GB 8.tar	03/23/2018 3:00 PM	8 GB
	test DO NOT PROCESS.txt	12/10/2016 9:46 AM	19 bytes
	testDONOTPROCESS.txt	12/10/2016 9:46 AM	19 bytes
	WebHelpDesk-12.5.1-x64.zip	07/13/2017 1:51 PM	292 MB

Need help?

Select Close

How do you use WebTrader? - Continued

- How can I receive WebTrader notifications:
 1. Click on drop-down arrow next to User Name in upper right
 2. Click on “User Settings”
 3. Check “Send an e-mail notification when a document is received”
 4. Click the “Save” button



Account Limitations

WebTrader

- WebTrader client software is required for sending submissions (ESG Support is able to troubleshoot issues with client software installation)
- Individual USER accounts
- Accounts should NOT be shared
- CROs, U.S. Agents, and Consultants
 - Need Letter of Authorization from client(s)
 - Need Letter of Non Repudiation from CRO / Agent company
 - WebTrader user can use 1 WebTrader Account for all clients

Server to Server (AS2)

- AS2 compliant software is required
- Certificate can be issued to any individual in the company
- ESG Support is NOT able to troubleshoot issues with AS2 software installation and configuration

What is the ESG HD support process?

1. Users have two ways to submit a ticket:
 - a) Send an email to the [ESG Help Desk](#)
 - b) Submit a ticket on the [ESG Help Desk website](#)
2. User will receive an auto-generated response, acknowledging receipt of ticket
3. ESG Help Desk will respond to the ticket
4. User will respond to ESG Help Desk
5. The SLA response time is 4 hours
 - 8:00 AM EST – 8:00 PM EST
 - Weekdays and Non-holidays
6. Resolution and Closure
 - a) Steps 3 and 4 may be repeated several times until closure
 - b) Any tickets not responded to by user in 7 days will be closed
7. System-related notifications



ESG Resources

- ESG Web Site:
 - <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm>
- ESG Email:
 - ESGHelpDesk@fda.hhs.gov
- ESG ListSrvs:
 - esg_as2_list@list.nih.gov
 - esg_wt_list@list.nih.gov
- WebTrader Registration Checklist:
 - <https://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/CreateanESGAccount/ucm114831.htm>
- AS2 Registration Checklist:
 - <https://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/CreateanESGAccount/ucm425405.htm>
- ESG Support Ticket Website:
 - <https://esghelpdesk.fda.gov>
- More information on Digital Certificates
 - <https://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/AboutESG/ucm334781.htm>

