FDA CVM Electronic Submission Systems

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For more information on Electronic Submissions please visit:
http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ElectronicSubmissions/default.htm
The FDA Manage Form is used to:

1. Register, Delete, and Change Stakeholder information for CVM's Electronic Submission System

OR

2. Validate a User’s Digital Signature for submitting electronically

*Your manage form will be submitted via ESG Test in order to grant you a ESG Production account. It must then be submitted again in Production in order to activate your ESS Account for electronic submission.
WebTrader Gateway - Test

Logging into the FDA Electronic Submissions Gateway (ESG) – Test Submissions Only

The URL to get to this screen is https://esgtest.fda.gov

Both User ID and Password are case sensitive
WebTrader Gateway - Production

Logging into the FDA Electronic Submissions Gateway (ESG)

The URL to get to this screen is https://esg.fda.gov

Both User ID and Password are case sensitive
Main WebTrader Software Screen

This is the WebTrader main screen that you do everything from.
Sending a Submission or Submissions to FDA

Select Send Document
WebTrader – Send Document Screen – 1 of 4

Send document
Select who will receive the document
Gateway: FDATST
Center:*
Submission type:*

Select the contents of the submission
Enter a path to a file or a directory. If a directory is entered, then the entire contents of the directory will be included in the submission. All the paths stored in the submission will be relative from the provided directory path unless an alternate root directory is entered.
Path:* 
Root directory:

Select a signing certificate
Current file: No certificate selected
New file: MyCertificate.p12 or MyPrivateKey.pfx

Send

Select CVM Center
WebTrader – Send Document Screen – 2 of 4

Select Electronic Submissions

Send document
Select who will receive the document
Gateway: FDATST
Center: CVM
Submission type: eSubmitter

Select the content
Enter a path to a file. If no path is entered, then the entire contents of the directory will be included in the submission. All the paths stored in the submission will be relative from the provided directory path unless an alternate root directory is entered.
Path: 
Root directory: 

Select a signing certificate
Current file: No certificate selected
New file: MyCertificate.p12 or MyPrivateKey.pfx

Send
WebTrader – Send Document Screen – 3 of 4

Send document

Select who will receive the document
Gateway: FDATST  
Center: CVM  
Submission type: Electronic_Submissions

Select the contents of the submission
Enter a path to a file or a directory. If a directory is entered, then the entire contents of the directory will be included in the submission. All the paths stored in the submission will be relative from the provided directory path unless an alternate root directory is entered.

Path: C:/Users/Shane.Burch/Desktop/Submission Directory/Submission  
Root directory Q:\Software\ESS_II\Certs\FDA-CVM-Test.p12 :tory/Submissi

Select a signing certificate
Current file: No certificate selected  
New file:  

Send

Click Send When All Fields are Filled In
Enter Certificate Password and Select OK

This can take a long time based on the size of submission or how busy the Gateway is. Please be patient.

SUCCESS
ESG Gateway Receipt

Initial Receipt from the Gateway - Click to see details

Click View document to view receipt
A new tab will open in your browser with a Message Disposition Notification – Has little useful information.

**Format options**

- [ ] Download the document
- [x] View document as text

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Date: Wed, 15 Apr 2015 18:59:34 GMT
From: esghelpdesk@fda.hhs.gov
Message-ID: <1429124373844.85310@fda105620.re2>
Subject: WenminChenWebTrader:22FDAIST
MIME-Version: 1.0
Content-Type: multipart/signed; boundary="-----_Part_68_16825728.1429124373856"; protocol="application/pkcs11"
EDINT-Features: CEM
X-Cyclone-From: 22FDAIST
X-Cyclone-To: WenminChenWebTrader
Content-Length: 2446

```
-----_Part_68_16825728.1429124373856
Content-Type: multipart/report;
    boundary="-----_Part_67_3326399.1429124373844";
    report-type=disposition-notification

-----_Part_67_3326399.1429124373844
Content-Type: text/plain; charset=us-ascii
```

This MDN (Message Disposition Notification) was automatically built on Wed, 15 Apr 2015 19:59:33 GMT in response to a message with id

You have the option to download the document as well.
ESG Acknowledgement #1

Opening the first submission acknowledgment – click on the first Acknowledgment link

Click View document to view acknowledgement
This is the Unique Identifier assigned to your transmission.

This first acknowledgement informs the submitter that the submission has been transferred to CVM’s ESS.
ESG Acknowledgement #2

Viewing the second acknowledgement (CVM ESS response) depends on the type of submission:

- **Electronic Submission**: PDF document
- **Adverse_Events_Reports**: Text document (Can be viewed in browser or downloaded and opened with standard text editor such as notepad)
- **eSubmitter**: requires you to open a ZIP file to view PDF

Click View document to view second acknowledgement.
For an **Adverse Events Reports** submission – your acknowledgement can be viewed in the browser. You are able to download a copy if you would like and open with standard text editor such as notepad.
For an eSubmitter submission - click the Download link to download a zip file of the document.

Please note: You may need a third party compression tool such as WinZip or 7-Zip to open the file.
This is the ESS Sponsor Notification form – Clicking the filename will open the Sponsor Notification PDF.
FDA CVM Digital Signature on Sponsor Notification

Opening the PDF file you will be shown the following screen stating that CVM has digitally signed the Sponsor Notification Document.

Clicking the Signature Properties will show you the next Screen.
Document Certification is valid, signed by CVM ESS II Signee.

Signed by: CVM ESS II Signee
Reason: I am the author of this document
Date: 2007/05/15 12:50:17 -04'00'
Location: Not available

Validity Summary:
- The document has not been modified since it was certified.
- The Signer’s Identity was valid when it was issued, but no revocation checks could be made to validate the identity at this time.
- Signature date/time are from the clock on the Signer’s computer.

Signature was created using Adobe Acrobat.
This is the ESS Sponsor Notification form. Notice that the form will be used for both submission rejections and acceptances.
This is the bottom of the Stakeholder Notification Receipt.
Notice that it is Digitally Signed.
WebTrader Hosted Solution (WTHS)

The Food and Drug Administration (FDA) Electronic Submissions Gateway (ESG) would like to notify users utilizing the WebTrader for FDA submissions of a new capability: the WebTrader Hosted Solution (WTHS). This new capability will be available starting June 1, 2014.

Important Things To Consider

- **WTHS** is a web-based solution that will eliminate the need for installing JRE (Java Runtime Environment) on the user's machine. The benefits of WTHS are:
  - WTHS eliminates the need for JRE installation and maintenance for WebTrader users' computers
  - WebTrader users can make submissions from both Windows and Mac operating systems
  - Users may make submissions from almost any Web Browser
  - WTHS does not replace WebTrader. It is an alternative to utilizing the computer-based application from a specific computer for making submissions to FDA. WTHS is an additional FDA service capability that can eliminate the need for the user computer JRE-based method for submitting to the WebTrader. It also provides submission process redundancy in case of a user not being able to access the JRE computer.
  - Users opting for WTHS will have an additional login (in addition to WebTrader login).
  - WTHS login session will have a limit of 60 minutes per login
  - WTHS option is recommended for submissions smaller than 250MB
  - Only one login session is allowed per user. Only one WTHS account is allowed per individual users. Users that have multiple WebTrader accounts will only be issued one WTHS account
  - The [WTHS Tutorial](http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm397489.htm) outlines how the WTHS and WebTrader account login and submission process works.

How do I request a WTHS account?

Send an email to [esghelpdesk@fda.hhs.gov](mailto:esghelpdesk@fda.hhs.gov) requesting access to WTHS. Please include your WebTrader User Id in the email request.

For more information regarding WTHS:

[http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm397489.htm](http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm397489.htm)