Sending Submissions to FDA CVM via the FDA Electronic Submission Gateway (ESG)

- WebTrader - Desktop Browser - Pages 2 to 11
- FDA Gateway Receipts - Pages 12 to 18
- FDA CVM ESS II Sponsor Notifications - Pages 19 to 21
- FDA CVM ESS II Digital Signatures - Pages 22 to 25
Logging in to the FDA ESG – Test Submissions Only

- The URL to get to this screen is https://esgtest.fda.gov
- This is the FDA Electronic Submissions Gateway Login Screen

NOTE:
Both the USER ID and the PASSWORD are Case Sensitive
Logging in to the FDA ESG – Production Submissions Only

- The URL to get to this screen is https://esg.fda.gov
- This is the FDA Electronic Submissions Gateway Production Login Screen

NOTE:
Both the USER ID and the PASSWORD are Case Sensitive
Main WebTrader Software Screen

- This is the Inbox where the ESG will deposit return messages
Sending a Submission or Submissions to FDA

- Click the ‘WEBTRADER’ icon
- Then click ‘Send Document’
WebTrader – Send Document Screen – 1 of 6

- Step 1 – Select ‘CVM’ from the ‘CENTER’ pull down list
WebTrader – Send Document Screen – 2 of 6

- Step 2 - Either enter in a submission directory or browse for a directory on your system.

- Step 3 – Select the ‘Electronic Submission’ pull down in the ‘Submission type’ window
Step 4 - Check filled-out information

The first time you send a document you must browse to a stored certificate file

Step 5 – Press the ‘Send’ button
WebTrader – Send Document Screen – 4 of 6

- Enter a Certificate Password and Select ‘OK’
Please be patient.

Do not close this window until told to do so.

This can take a long time based on the size of submission or how busy the Gateway is.
WebTrader – Send Document Screen – 6 of 6

- This is the ‘Upload Progress’ screen complete indicator
- You can now press the ‘Close’ button
ESG Return Message #1

Initial Receipt from the Gateway – Not usable until you rename the file

Click on Details
The Next Screen appears
Documents in Inbox

- 1178824949601.4143@llntap01.pdf
  - From: FDATST
  - Date: May 10, 2007 5:18:56 PM
  - Size: 2331 bytes
  - Signed with certificate FDATST using SHA1 digest algorithm

- 1178826071339.1587@llntap02.pdf
  - From: FDATST
  - Date: May 10, 2007 6:24:57 PM
  - Size: 2331 bytes
  - Signed with certificate FDATST using SHA1 digest algorithm

- Receipt for Submission Directory.tar.gz
  - From: FDATST
  - To: FDA CVM Test #1
  - Date: May 15, 2007 9:36:42 AM
  - Size: 2331 bytes
  - Signed with certificate FDATST using SHA1 digest algorithm

- 1179236200500.2448@llntap02.txt
  - From: FDATST
  - Date: May 15, 2007 9:41:06 AM
  - Size: 2331 bytes
  - Signed with certificate FDATST using SHA1 digest algorithm

- 1179236200500.2448@llntap02.zip
  - From: FDATST
  - Date: May 15, 2007 12:52:10 PM
  - Size: 2331 bytes
  - Signed with certificate FDATST using SHA1 digest algorithm

Move to trash | Move/Copy
to Select a folder

5 documents

Receipt for Submission Directory.tar.gz

From: FDATST
To: FDA CVM Test #1
Date: May 15, 2007 9:36:42 AM
Size: 2331 bytes
Type: Receipt
Protocol: Secure file
Signed: Signed with certificate FDATST using SHA1 digest algorithm
Message ID: <1179236202549.2457@llntap02>

View document
Rename document
Move document to trash
Hide details

Center for Veterinary Medicine
Add ".txt" to the end of the Receipt file name – Press the Green check box
You can open the text file or save it to your local system
This is a Message Digest Notification – Has little useful information
Opening the Second Gateway Receipt – Just Click on the File name
This second Gateway notification informs the submitter that the submission has been transferred to CVM’s ESS.

This is the Unique Identifier assigned to your transmission.

This is the ESG Official Receipt timestamp to your transmission.
Viewing the CVM ESS response requires you to open a ZIP file
Clicking on the filename opens the Zip program on your PC. You can save the zipfile or open it.
This is the ESS Sponsor Notification form – Notice that the filename matches the file name you submitted. Clicking the filename will open the Sponsor Notification PDF. If you submitted multiple submissions within one transmission they will be bundled up within the Zip file.
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 Status

This document has special status or special features.

Certification VALID.

This document was Certified with the Digital Signature of:

Name: CVM ESS II Signee
Organization: Center for Veterinary Medicine
Issued by: CVM ESS II Signee

The Digital Signature is valid and the document has not been subsequently tampered with.

Click 'Signature Properties' to view more information about the signature and its validity. Reliance upon this Certified document requires your acceptance of the terms described when you click 'Legal Notice'.

To access signature information later, open the Signatures Tab on the left, select the Certifying Signature and choose 'Properties' from the Options menu.
This is CVM’s digital Signature applied to the Sponsor Notification Receipt.
This is the ESS II Sponsor Notification form. Notice that the form will be used for both submission rejections and acceptance.
FDA CVM Digital Signature on Sponsor Notification

This is the bottom of the Stakeholder Notification Receipt. Notice that it is Digitally Signed.