

FDA CVM Electronic Submission Systems

- ▶ 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://esqtest.fda.gov>
- ▶ This is the FDA Electronic Submissions Gateway Login Screen

NOTE:

Both the USER ID and the PASSWORD are Case Sensitive

FDA U.S. Food and Drug Administration Department of Health and Human Services

FDA Electronic Submissions Gateway

User ID

Password

I agree to the terms set forth in the System Notification below.

Remember my user ID

Login

Licensed to: [FDA](#)

Pop-up blocking software for your browser may interfere with this product. You may want to disable or uninstall such software.

YOU ARE ENTERING THE FDA ELECTRONIC SUBMISSIONS GATEWAY TEST ENVIRONMENT. THIS ENVIRONMENT IS TO BE USED FOR TEST SUBMISSIONS ONLY.



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

FDA U.S. Food and Drug Administration Department of Health and Human Services

FDA Electronic Submissions Gateway

User ID

Password

I agree to the terms set forth in the System Notification below.

Remember my user ID

Login

Licensed to: [FDA](#)

Pop-up blocking software for your browser may interfere with this product. You may want to disable or uninstall such software.



Main WebTrader Software Screen

- ▶ This is the Inbox where the ESG will deposit return messages



WebTrader Help Logout

Documents in Inbox

Open folder Select a folder

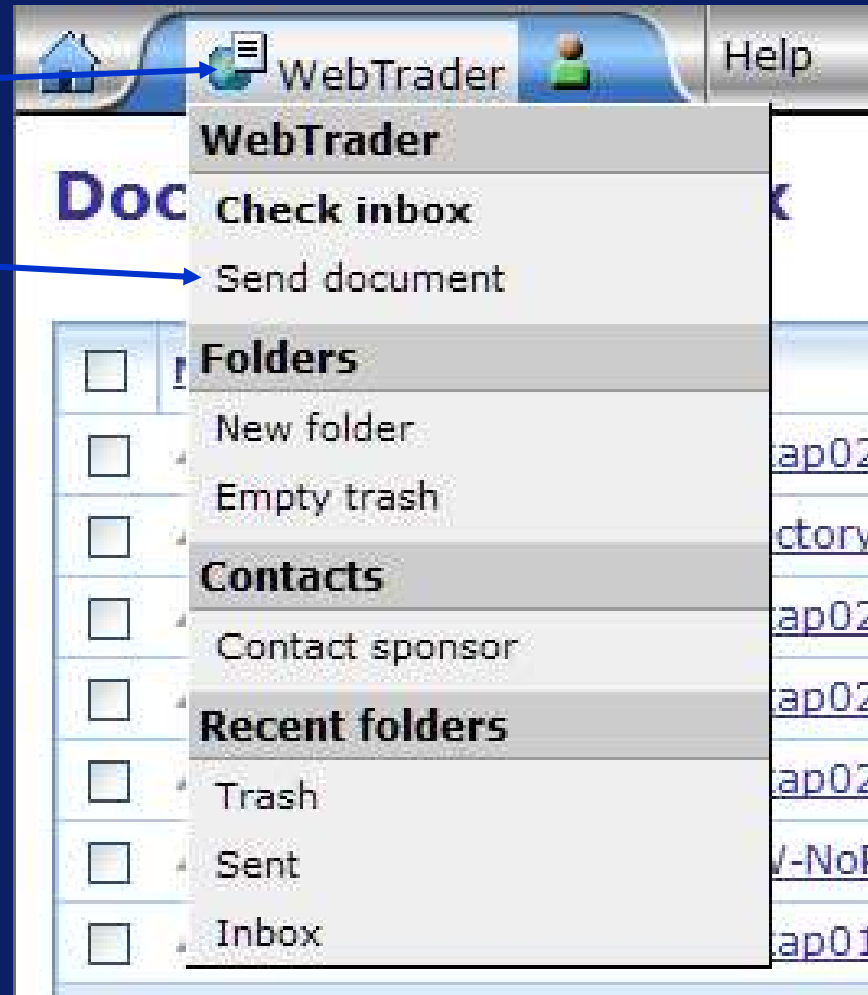
<input type="checkbox"/>	Name	From	Size	Date ▲	
<input type="checkbox"/>	1178650806297.1105@llntap02.txt	FDATST	426 bytes	May 8, 2007 3:07:01 PM	Details
<input type="checkbox"/>	Receipt for Submission Directory.tar.gz	FDATST	3 KB	May 8, 2007 3:37:01 PM	Details
<input type="checkbox"/>	1178650806297.1105@llntap02.zip	FDATST	30 KB	May 8, 2007 3:37:03 PM	Details
<input type="checkbox"/>	1178653019812.1134@llntap02.txt	FDATST	425 bytes	May 8, 2007 3:42:03 PM	Details
<input type="checkbox"/>	1178653019812.1134@llntap02.zip	FDATST	30 KB	May 8, 2007 3:42:03 PM	Details
<input type="checkbox"/>	Receipt for AD7-Change PW-NoPassword.pdf	FDATST	3 KB	May 10, 2007 3:22:30 PM	Details
<input type="checkbox"/>	1178824949601.4143@llntap01.txt	FDATST	426 bytes	May 10, 2007 3:26:54 PM	Details

Move to trash | Move/Copy to Select a folder 7 documents



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

Send document

Select who will receive the document

Gateway: FDATST

Center:*

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:

Submission type:*

Select a signing certificate

Current file: Q:\Software\ESS_II\Certs\FDA-CVM-Test-1.p12

New file:

MyCertificate.p12 or MyPrivateKey.pfx

Select who will receive the document

Gateway: FDATST

Center:*

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:

Submission type:*

- CBER
- CDER
- CDRH
- CFSAN
- CVM
- OOPD
- Testing



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

The screenshot shows the 'Send document' interface in the WebTrader application. The interface includes the following sections:

- Select who will receive the document:** Gateway: FDATST, Center: * [dropdown]
- 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: * [text input] [Browse...]
Root directory: [text input] [Browse...]
- Select a signing certificate:** Current file: Q:\Software\ESS_II\Certs\FDA-CVM-Test-1.p12
New file: [text input] MyCertificate.p12 for MyPrivateKey.pfx

The 'Submission type' dropdown menu is open, showing 'Electronic Submissions' selected. An 'Open' file dialog box is overlaid on the right, showing the 'Desktop' location with a file list including 'Submission Directory'. The 'File Name' field contains 'Submission Directory' and 'Files of Type' is set to 'All Files'. Blue arrows indicate the flow from the text instructions to the 'Browse...' buttons, the 'Submission type' dropdown, and the 'Open' dialog box.



WebTrader – Send Document Screen – 3 of 6

- ▶ 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

Send document

Select who will receive the document

Gateway: FDATST
Center:* CVM

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:\Documents and Settings\hconrad\Desktop\Submission Dire Browse...

Root directory: C:\Documents and Settings\hconrad\Desktop\Submission Dire Browse...

Submission type: Electronic Submissions

Select a signing certificate

Current file: Q:\Software\ESS_II\Certs\FDA-CVM-Test-1.p12
New file: Browse...
MyCertificate.p12 or MyPrivateKey.pfx

Send



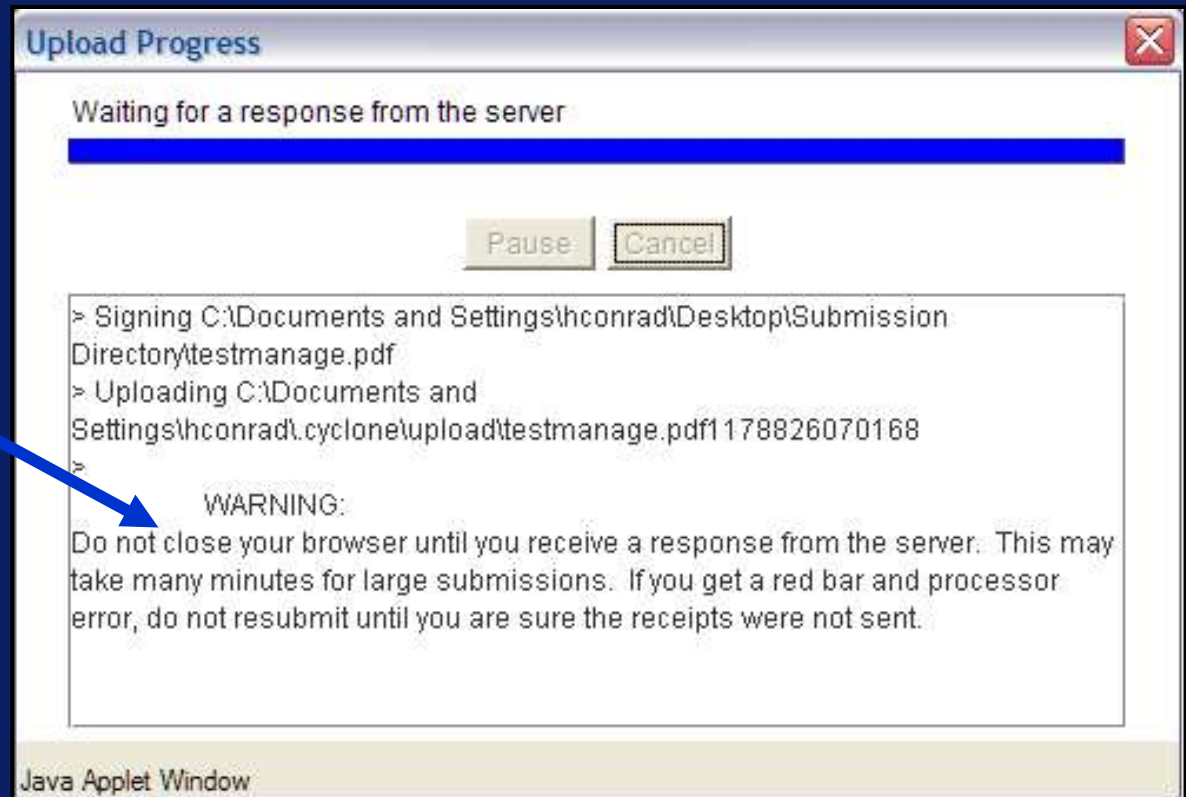
WebTrader – Send Document Screen – 4 of 6

- Enter a Certificate Password and Select 'OK'



WebTrader – Send Document Screen – 5 of 6

- 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

Cyclone - FDA CVM Test #1/Howard Conrad on esgtest.fda.gov - Microsoft Internet Explorer

Address <https://esgtest.fda.gov/ui/webtrader/FolderView?name=webtrader.folder.inbox&download=8497463&showDetails=&showParty=> Go Links

WebTrader Help Logout

Documents in Inbox

Open folder

<input type="checkbox"/>	Name	From	Size	Date ▲	
<input type="checkbox"/>	1178824949601.4143@lntap01.pdf	FDATST	56 KB	May 10, 2007 5:18:56 PM	Details
<input type="checkbox"/>	1178826071339.1587@lntap02.pdf	FDATST	56 KB	May 10, 2007 6:24:57 PM	Details
<input type="checkbox"/>	Receipt for Submission Directory.tar.gz <i>New</i>	FDATST	3 KB	May 15, 2007 9:36:42 AM	Details
<input type="checkbox"/>	1179236200500.2448@lntap02.txt	FDATST	425 bytes	May 15, 2007 9:41:06 AM	Details

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

Click on Details
The Next Screen appears



Cyclone - FDA CVM Test #1/Howard Conrad on esgtest.fda.gov - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Search Favorites

Address <https://esgtest.fda.gov/ui/webtrader/FolderView?name=webtrader.folder.inbox&download=8497463&showDetails=&showParty=> Go Links

WebTrader Help Logout

Documents in Inbox

Open folder

<input type="checkbox"/> Sort by	Date	Sort ▲
<input type="checkbox"/> 1178824949601.4143@lntap01.pdf FDATST	May 10, 2007 5:18:56 PM	Details
<input type="checkbox"/> 1178826071339.1587@lntap02.pdf FDATST	May 10, 2007 6:24:57 PM	Details
<input type="checkbox"/> Receipt for Submission Directory.tar.gz <i>New</i> FDATST	May 15, 2007 9:36:42 AM	Details
<input type="checkbox"/> 1179236200500.2448@lntap02.txt FDATST	May 15, 2007 9:41:06 AM	Details
<input type="checkbox"/> 1179236200500.2448@lntap02.zip <i>New</i> FDATST	May 15, 2007 12:52:10 PM	Details

Move to trash | Move/Copy to

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
[Show original document](#)

Protocol: Secure file
Signed: Signed with certificate [FDATST](#) using SHA1 digest algorithm
Message ID: <1179236202549.2457@lntap02>

[View document](#)
[Rename document](#) ← **Click on Rename**
[Move document to trash](#)
[Hide details](#)



Cyclone - FDA CVM Test #1/Howard Conrad on esgtest.fda.gov - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <https://esgtest.fda.gov/ui/webtrader/FolderView?name=webtrader.folder.inbox&download=8497463&showDetails=&showParty=> Go Links

WebTrader Help Logout

Documents in Inbox

Open folder

<input type="checkbox"/>	Sort by <input type="text" value="Date"/>	Sort ▲
<input type="checkbox"/>	1178824949601.4143@lntap01.pdf FDATST	May 10, 2007 5:18:56 PM Details
<input type="checkbox"/>	1178826071339.1587@lntap02.pdf FDATST	May 10, 2007 6:24:57 PM Details
<input type="checkbox"/>	Receipt for Submission Directory.tar.gz.txt FDATST	May 15, 2007 9:11:06 AM Details
<input type="checkbox"/>	1179236200500.2448@lntap02.txt FDATST	May 15, 2007 9:11:06 AM Details

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
[Show original document](#)

Protocol: Secure file
Signed: Signed with certificate [FDATST](#) using SHA1 digest algorithm
Message ID: <1179236202549.2457@lntap02>

[View document](#)
[Rename document](#)
[Move document to trash](#)
[Hide details](#)

Click to rename this document

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




```
Message-ID: <1178826072435.1596@llntap02>
Date: Thu, 10 May 2007 19:41:12 GMT
From: esgpreptest@fda.gov
Subject: FDACVMTest;ZZFDATST
Mime-Version: 1.0
Content-Type: multipart/signed; micalg=sha1; protocol="application/pkcs7-signature";
X-Cyclone-From: ZZFDATST
X-Cyclone-To: FDACVMTest
Content-Length: 1963

-----=_Part_40_8666713.1178826072436
Content-Type: multipart/report; report-type=disposition-notification;
        boundary="-----=_Part_39_17211960.1178826072435"

-----=_Part_39_17211960.1178826072435
Content-Type: text/plain; charset=us-ascii

This MDN (Message Disposition Notification) was automatically built on
Thu, 10 May 2007 19:41:12 GMT in response to a message with id
<21704474.1178826070188.JavaMail.hconrad@cvw5117619> received from
ZZFDATST on Thu, 10 May 2007 19:41:11 GMT.
Unless stated otherwise, the message to which this MDN applies
was successfully processed.

-----=_Part_39_17211960.1178826072435
Content-Type: message/disposition-notification

Original-Message-ID: <21704474.1178826070188.JavaMail.hconrad@cvw5117619>
Disposition: automatic-action/MDN-sent-automatically; processed
Received-Content-MIC: mmLnaL4gA6PKJplNgUvMf3XgtSY=, sha1

-----=_Part_39_17211960.1178826072435--

-----=_Part_40_8666713.1178826072436
Content-Type: application/pkcs7-signature
Content-Transfer-Encoding: binary
```

This is a Message Digest Notification – Has little useful information



Cyclone - FDA CVM Test #1/Howard Conrad on esgtest.fda.gov - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Refresh Print Mail W

Address <https://esgtest.fda.gov/ui/webtrader/FolderView?name=webtrader.folder.inbox&download=8497463&showDetails=&showParty=> Go Links

WebTrader Help Logout

Documents in Inbox

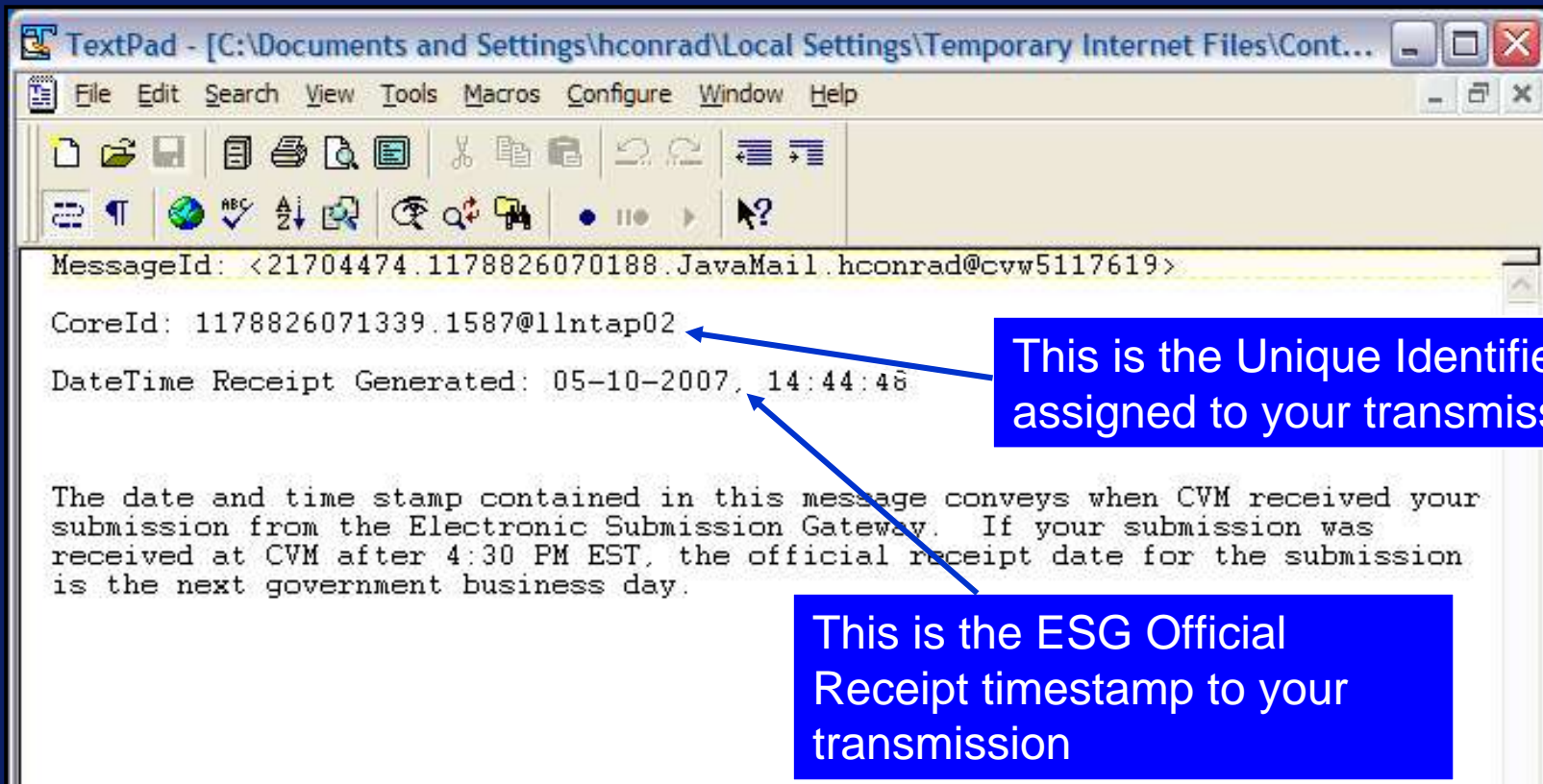
Open folder

<input type="checkbox"/>	Name	From	Size	Date ▲	
<input type="checkbox"/>	1178824949601.4143@lntap01.pdf	FDATST	56 KB	May 10, 2007 5:18:56 PM	Details
<input type="checkbox"/>	1178826071339.1587@lntap02.pdf	FDATST	56 KB	May 10, 2007 6:24:57 PM	Details
<input type="checkbox"/>	Receipt for Submission Directory.tar.gz <i>New</i>	FDATST	3 KB	May 15, 2007 9:36:42 AM	Details
<input type="checkbox"/>	1179236200500.2448@lntap02.txt	FDATST	425 bytes	May 15, 2007 9:41:06 AM	Details

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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



Cyclone - FDA CVM Test #1/Howard Conrad on esgtest.fda.gov - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Search Favorites

Address <https://esgtest.fda.gov/ui/webtrader/FolderView?name=webtrader.folder.inbox&download=8497463&showDetails=&showParty=> Go Links

WebTrader Help Logout

Documents in Inbox

Open folder

<input type="checkbox"/> Sort by	Date	Sort ▲
<input type="checkbox"/> 1178824949601.4143@lntap01.pdf	May 10, 2007 5:18:56 PM	Details
<input type="checkbox"/> 1178826071339.1587@lntap02.pdf	May 10, 2007 6:24:57 PM	Details
<input type="checkbox"/> Receipt for Submission Directory.tar.gz <i>New</i>	May 15, 2007 9:36:42 AM	Details
<input type="checkbox"/> 1179236200500.2448@lntap02.txt	May 15, 2007 9:41:06 AM	Details
<input type="checkbox"/> 1179236200500.2448@lntap02.zip <i>New</i>	May 15, 2007 12:52:10 PM	Details

Move to trash | Move/Copy to

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
[Show original document](#)

Protocol: Secure file
Signed: Signed with certificate [FDATST](#) using SHA1 digest algorithm
Message ID: <1179236202549.2457@lntap02>

[View document](#)
[Rename document](#)
[Move document to trash](#)
[Hide details](#)

Viewing the CVM ESS response requires you to open a ZIP file



Documents in Inbox

Open folder ▼


Sort by Date ▼ [Sort ▲](#)


<input type="checkbox"/>	1178824949601.4143@llntap01.pdf FDATST	May 10, 2007
<input type="checkbox"/>	117882607... FDATST	
<input type="checkbox"/>	Receipt for Submission Directory.tar.gz FDATST	
<input type="checkbox"/>	1179236200... FDATST	
<input type="checkbox"/>	1179236200... FDATST	

[Move to trash](#) | [Move to](#)

File Download

Do you want to open or save this file?

 Name: 1179236200500[1].2448@llntap02.zip
Type: WinZip File
From: esgtest.fda.gov

 While files from the Internet can be useful, some files can potentially hamper your computer. If you do not trust the source, do not open or save this file. [What's the risk?](#)

Receipt for Submission Directory.tar.gz.txt

From: [FDATST](#)
To: [FDA CVM Test #1](#)

15, 2007 9:36:42 AM
bytes
ript
[original document](#)

Secure file
Signed with certificate [FDATST](#)
using SHA1 digest algorithm
<1179236202549.2457@llntap02>

[ent](#)
[ument](#)
[ent to trash](#)

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



Date: Tue
To: Sul
Subject: FD


The Center
your submit
documents t
review divisi

Memo
Your subn

Document Status

This document has special status or special features.

Document Status

 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.

Do not show this dialog next time this document is opened.

Document Status icons are always located at the bottom-left corner of the document window. Click a Document Status icon to view this dialog again.

[Legal Notice...](#) [Signature Properties...](#)

[Close](#)

Clicking the Signature Properties will show you the next Screen

FDA CVM Digital Signature on Sponsor Notification

- ▶ This is CVM's digital Signature applied to the Sponsor Notification Receipt.



FDA CVM Digital Signature on Sponsor Notification

This is the ESS II Sponsor Notification form. Notice that the form will be used for both submission rejections and acceptance.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date: Tue May 15 12:50:17 EDT 2007

TO: Submitter

Subject: FDA CVM ESS – Stakeholder Submission Notification

The Center for Veterinary Medicine, Food and Drug Administration acknowledges the receipt of your submission to the FDA CVM Electronic Submission System. The following information documents the state of your submission. If you have any questions, please contact either the review division or the Electronic Submission Coordinator at 301-827-8277.

Memo:

Your submission has been rejected. The submitted form must be version 5.0 or later.

Date/Time Received:	05-15-2007, 09:38:52		
Transmission Identifier:	1170238200500.2448@lntap02-1-1		
Submission Identifier:	N/A	Review Division:	
Applicant Name:			
Chemical Name:			
Submitted Document Type:			
Submission Type:			
Correspondence Date:		CVM Due Date:	
Parent Submission:		Reference Submission:	
Stakeholder File Name:	Signature Validation.pdf		
Multi-Document Index:			



FDA CVM Digital Signature on Sponsor Notification

Notes:

Stakeholder Receipt (05/07) 5.0

Digital Signature:
Document Certified by CVM ESS II Signee.
Digitally signed by CVM ESS II Signee
Date: 2007.05.15 12:50:17 EDT
Reason: I am the author of this document

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

