

FDA CVM ESS II

Screen Shot

Demo

Guidance	Export Data	Import Data	Reset Form
DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Center for Veterinary Medicine		Electronic Submission System Participant Management Form	
		Form Approved: OMB No. 0910-0054 Expiration Date: 3/31/2010	
<small>PAPERWORK REDUCTION ACT STATEMENT: A Federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a current valid OMB control number. The public reporting burden for the collection of information is estimated to vary from 5 to 10 minutes, with an average of 8 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary information, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information to the Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.</small>			

I. SECTION I – Registration / Information:

Select 'Add', 'Delete' or 'Change' then complete the required information.

ADD <Coordinators Only>
 DELETE <Coordinators Only>
 CHANGE

Stakeholder Name:	<input type="text"/>
Stakeholder Company Name:	<input type="text"/>
Company Address 1:	<input type="text"/>
Company Address 2:	<input type="text"/>
City:	<input type="text"/>
St. Prov:	<input type="text"/>
Postal Code:	<input type="text"/>
Country:	<input type="text"/>
Stakeholder Phone:	<input type="text"/>
Stakeholder Email Address:	<input type="text"/>

II. SECTION II – Digital Signature Validation:

I certify that the applied digital signature is mine.

Stakeholder Name:	<input type="text" value="Howard"/>	<input type="text" value="Conrad"/>
Stakeholder Email Address:	<input type="text" value="howard.conrad@fda.hhs.gov"/>	

Digitally signed by Howard Conrad
 DN: cn=Howard Conrad, o=US, o=Booz Allen Hamilton, email=howard.conrad@hhs.fda.gov
 Reason: I am the author of this document
 Location: Rockville, MD
 Date: 2007.05.15 09:34:38 -04'00'



FDA Electronic Submissions Gateway

Both User ID and
Password are
case sensitive

User ID

Password

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

Remember my user ID

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.**

WebTrader Help Logout

Documents in Inbox

Open 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](#) 7 documents

This is the WebTrader main screen that you do everything from.

Select Send Document

The screenshot shows the top navigation bar of the WebTrader application. It includes a home icon, the text 'WebTrader', a user profile icon, and a 'Help' button. A dropdown menu is open, listing various actions and categories. The 'Send document' option is highlighted, and an arrow from the 'Select Send Document' text box points to it. The menu items are: 'WebTrader', 'Check inbox', 'Send document', 'Folders', 'New folder', 'Empty trash', 'Contacts', 'Contact sponsor', 'Recent folders', 'Trash', 'Sent', and 'Inbox'. The background shows a list of documents with checkboxes and partial titles like 'ap02', 'ctory', 'ap02', 'ap02', 'ap02', 'y-NoF', and 'ap01'.

- WebTrader
- Check inbox
- Send document
- Folders
 - New folder
 - Empty trash
- Contacts
 - Contact sponsor
- Recent folders
 - Trash
 - Sent
 - Inbox

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 CVM Center

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:

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

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:*

Browse...

Root directory:

Browse...

Submission type:*

Select a signing certificate

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

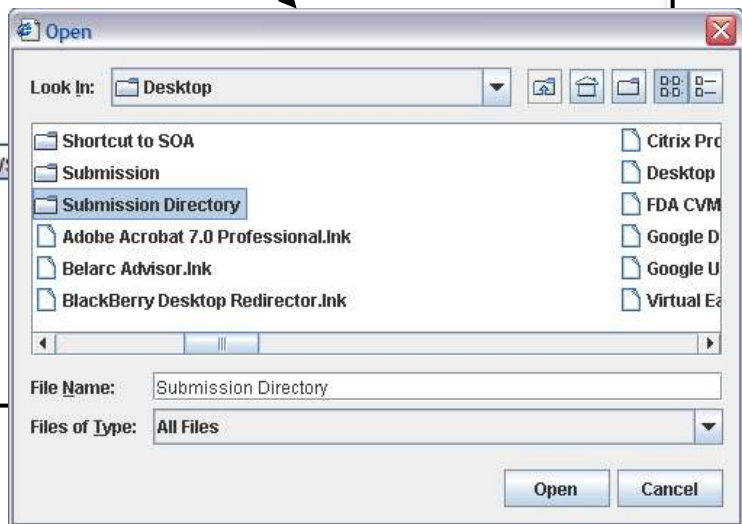
New file:

MyCertificate.p12 or MyPrivateKey.pfx

Browse...

Send

Submission type:*
Electronic Submissions



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

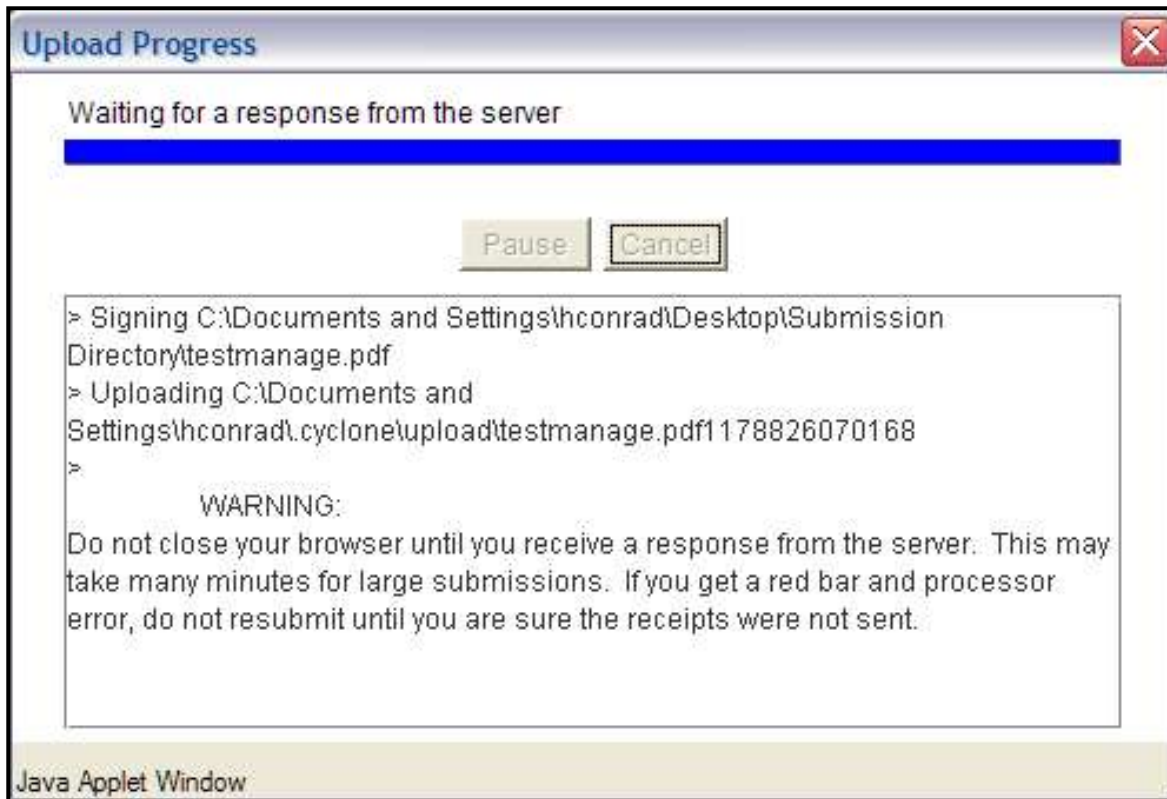
Select a signing certificate

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

Send ← Press Send When 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

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"/>	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

[Move to trash](#) | [Move/Copy to](#) 4 documents

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 <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 <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 <input type="text" value="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
[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 on Rename

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 9:41:06 AM Details
<input type="checkbox"/>	1179236200500.2448@lntap02.txt FDATST	May 15, 2007 9:41:06 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 Search Favorites

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

WebTrader Help Logout

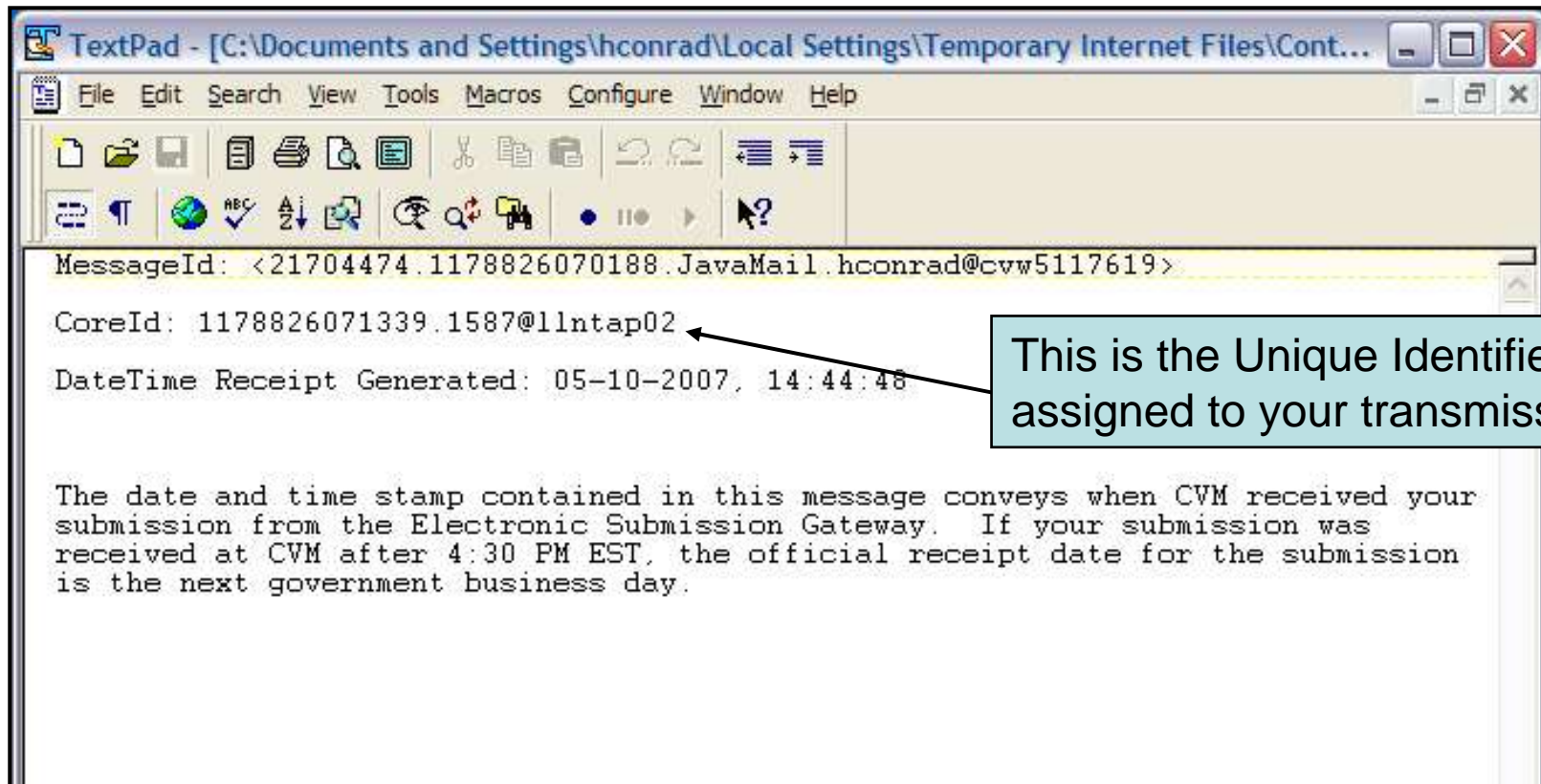
Documents in Inbox

Open folder

<input type="checkbox"/>	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

[Move to trash](#) | [Move/Copy to](#) 4 documents

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 Go Links

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

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 ▼

<input type="checkbox"/>	Sort by <input type="text" value="Date"/> ▼	Sort ▲	
<input type="checkbox"/>	1178824949601.4143@lntap01.pdf	May 10, 2007	Receipt for Submission Directory.tar.gz.txt From: FDATST To: FDA CVM Test #1
<input type="checkbox"/>	117882607...		15, 2007 9:36:42 AM bytes ript y original document
<input type="checkbox"/>	Receipt for S...		Secure file Signed with certificate FDATST using SHA1 digest algorithm <1179236202549.2457@lntap02>
<input type="checkbox"/>	1179236200...		ent ument ent to trash
<input type="checkbox"/>	1179236200...		

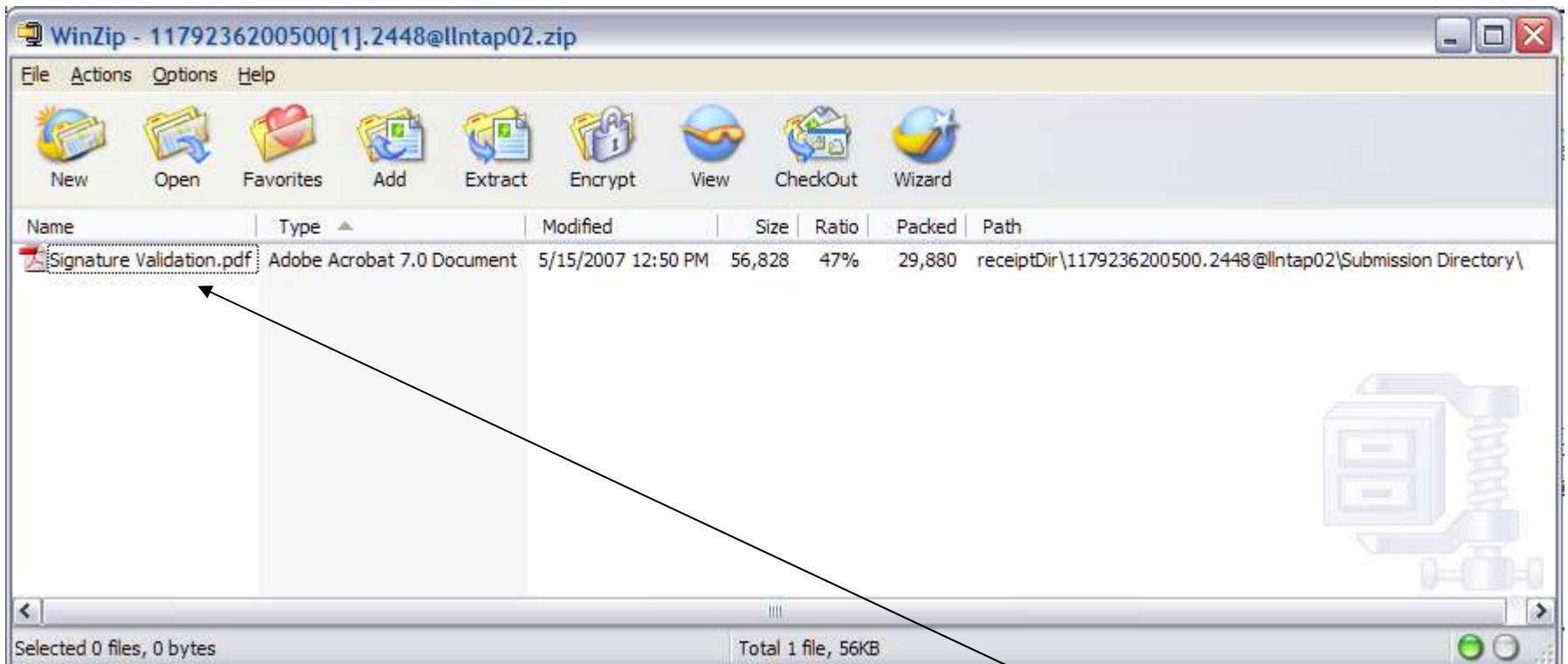
File Download

Do you want to open or save this file?

 Name: 1179236200500[1].2448@lntap02.zip
Type: WinZip File
From: esgtest.fda.gov

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

Clicking on the filename opens the Zip program on your PC. You can save the zip file 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

Signature Properties



Document Certification is valid, signed by CVM ESS II Signee.

Summary Document Signer Date/Time Legal

Signed by: CVM ESS II Signee




Show Certificate...

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.

Verify Signature

Close



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:	1179236200500.2448@llintap02-1-1		
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:			

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


Notes:

[Empty rectangular box for notes]

Stakeholder Receipt (05/07) 5.0

Digital Signature:

Document Certified by CVM ESS II Signee.
Digitally signed by CVM ESS II Signee
Date: 2007.05.05 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.